EXHIBIT C

01

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

RE: ETHICON, INC, PELVIC, REPAIR SYSTEM PRODUCTS REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	)	Master File No. 2:12-MD-02327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN THE WAVE 1 OF MDL 200: TINA and KENNETH MORROW, Plaintiffs, vs. ETHICON, INC., ET AL., Defendants.	)	Case No. 2:12-cv-00378

VIDEOTAPED DEPOSITION OF NATHAN W. GOODYEAR, M.D.

March 4, 2016
8:15 a.m. to 12:37 p.m.

TRACY IMAGING
KNOXVILLE, TENNESSEE

Michele Faconti, RPR, LCR (667)

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Also Present: Ernie Tracy, Videographer

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STIPULATION

The deposition of Nathan W. Goodyear, M.D., called as a witness by the Defendants, pursuant to all applicable rules of the 4th day of March, 2016, at the offices of Tracy Imaging, Knoxville, Tennessee, before Michele Faconti, RPR, Licensed Court Reporter and Notary Public in and for the State of Tennessee.

It being agreed that Michele Faconti, a Tennessee Licensed Court Reporter, may report the deposition in machine shorthand, afterwards reducing the same to typewritten form. All objections, except as to the form of the question, are reserved to on or before the hearing.

It being further agreed that all formalities as to notice, caption, certificate, transmission, etcetera, are expressly waived, EXCLUDING the reading of the completed deposition by the witness, and the signature of the witness.

(08:15 A.M.)

VIDEOGRAPHER: Okay. We are on the record. Today's date is March the 4th, 2016. The time on the camera is 8:15 a.m. My name is Ernie Tracy. I am a videographer for Golkow Technologies.

This deposition is being held in Knoxville, Tennessee in the case of Tina Morrow versus Ethicon, Incorporated. And the deponent today is Dr. Nathan Goodyear, M.D. And the attorneys will now identify themselves for the record.

MS. MOORE: Kim Moore on behalf of the defendants.

MS. CAPODICE: Cami Capodice on behalf of defendants.

MS. KOTT: Mikalia Kott on behalf of Tina Morrow and her husband Kenneth Morrow; Charlene Taylor, Teri and Johnny Shively, and Dina Bennett, the plaintiffs.

MR. KOTT: My name is Joe Kott. I'm here on behalf of the plaintiffs, including the MDL consortium, in addition to those identified by my colleague.

Good morning, everyone.

WHEREUPON,

Nathan W. Goodyear, M.D.,

having been first duly sworn, as hereinafter certified, testified as follows:

DR. GOODYEAR: I do.

EXAMINATION

BY MS. MOORE:

Q. Good morning, Dr. Goodyear.

A. Good morning.

Q. Got a chance to get a little bit of rest last night?

A. Of course.

Q. Going to continue today asking you questions about the care, treatment of your patients. I believe next up we have Mrs. Tina Morrow. So we'll be focusing on her. But as you are aware, these cases have been cross noticed, so your testimony in one can apply to testimony in another or all.

A. Uh-huh.

Q. And have you had a chance to do any homework, research last night after you got home on any of the issues in the case?

A. Sure. As I would anytime, I go back and research some things.

Q. All right. What did you research last night?

A. Researched basically -- there was great debate about erosion rate quoted. And so I came across, again, just an example of some of the literature available at that time that helped to form my opinion of the 3 to 5 percent erosion rate. Was a proven study out of 2007 looking at -- it was a multicenters trial of Prolift implantation and they found their erosion rate to be 4.7 percent.

Q. 4.7 percent. And do you have --

A. I printed it out.

Q. And so this is research you did?

A. Not research that I did. It was research that was published that I -- was used as a part of my --

Q. Listen to my question. This was research you did last night after I asked you a question to try to find some research to help you respond?

A. It was a study and range that was similar to what was available at the time that I made that.

Q. Listen to my question, please. You left

here last night after I asked you questions based on your report and the information contained in your report. And you did some research last night to find some additional support?

A. Yeah, but this was similar to what was available to me at the time.

Q. And I understand that. That's your opinion. But I'm just saying, you did not do that research until last night?

A. It's not my opinion, that was available at the time.

Q. Well, you did not do the research and find the article?

MR. KOTT: He means scientific research, not literary.

MS. MOORE: Counsel, object to form.

MR. KOTT: I understand, I'm trying to move things along.

MS. MOORE: And I appreciate that you and I are trying to make flights today, but --

THE WITNESS: If your research is identified as a Google search --

BY MS. MOORE:

Q. Yes.

A. -- I'm talking about scientific research.

Q. What did you do last night -- did you have this opinion yesterday, did you have this paper yesterday?

A. The 3.5 percent is consistent with what was published in that.

Q. That was not my question. I'm not asking what is consistent.

A. Okay.

Q. I'm asking, did you go home last night and do some research to find additional support for your opinion?

A. I did a Google search.

Q. Okay. You did a Google search. And you found that the Prolift 2007 article referencing erosion rates was around 4.7?

A. No, not around. It was 4.7 in a multitrial -- multicenter trial study.

Q. And it was in the 2007 time period?

A. It was published in 2007.

Q. All right. Where was it published?

A. International -- I printed it out. It's International Urology Journal, I believe.

Q. We'll find it and attach it.

A. It's been printed out.
Q. And what other research did you find?
A. I just did a quick Google search. That was all. Actually, there was another review article. I'm sorry, it was a review article of the history of mesh that basically went through the different aspects of mesh.
Q. And do you remember the authors of any of these two articles?
A. No, but I can print that out.
Q. On a break I'd ask that you do that. And history of mesh, it was also in the 2007 time period?
A. I'd have to go back. I can't remember the time on that one.
Q. Do you remember the author on the first one?
A. Yes. Give me just a moment. Does that every time. Asks me to sign in every time.
Q. Do you need to take a break, sir?
A. No, give me just a moment.
MS. MOORE: Why don't we go off the record.
VIDEOGRAPHER: We are going off the

record. The time is 8:20.

(Off the record.)

VIDEOGRAPHER: Okay. We are back on the record. The time is 8:20.

THE WITNESS: I'm not sure how to pronounce it, but it's F-a-t-t-o-n. Fatton. First initial is B. Fatton B., et al., the International Urogynecological Journal of Pelvic Floor Dysfunction, published in 2007.

BY MS. MOORE:

Q. Okay. And you are -- this is the article you found last night?

A. On a Google search.

Q. And you did not reference this, it's not on your reliance list?

A. I did not cross reference it with the reliance list. I was just looking to see is something just on a Google search. They are there available to anybody to support what I reference as was readily available in the literature at the time. And it was right there on the first page.

Q. You were looking for support for your reference of 3 to 5 percent?

A. No.

Q. What were you looking for? Help me there.
A. What I was doing was to see anybody that wasn't attuned to looking in the scientific literature through PubMed, etcetera.
Q. What --
MR. KOTT: Object. Please let him finish his answers.
A. Somebody that is just in the medical field knows where to go into the scientific literature to look in the science. I'm saying a nonscientific person. If I'm just nonscientific and I want to go, wow, let me just Google and see if anything pops up. And so I took it from a nonscientific medical perspective to say, is there anybody that just says, you know what, I'm just curious and it popped up. First page, so, there you go.
Q. And why didn't you include that in your report beforehand?
A. Like I said, I have not cross-referenced that with the reliance. It was late.
Q. And so you're saying you don't know if it's on your reliance list or not?
A. That is correct.
Q. As we sit here today, when you were asked

about that number, you were unable to identify that yesterday on the reliance list?

A. Correct. I did not identify that particular study. But, as I said, that is very similar to the reference range that was available at the time. That's why that percentage was listed there.

Q. Okay. So I'm a little confused now. You're saying that your range was supported by what was in the literature?

A. I told you based on -- the Prolift was marketed as a revolutionary procedure. There was limited data available to go to as this procedure came to market. There was data. The data supported that range, but the majority of the recommendations about the erosion rates and complication rates came from the manufacturer of that procedure. Because they brought it to market. They were behind the studies that brought it to market. And so they would have been our greatest resource to turn to.

Q. Have you gone through the literature and looked at all the papers on erosion rates during that time period?

A. Have I looked at all of them?

Q. Uh-huh.

A. No. That would be an unfair statement for anybody to make.

Q. Okay. I was just wondering why you said the majority of the papers were by the manufacturer?

A. Well, when a new product comes as it recurs vis-a-vis FDA approval, they are going to be the money behind -- the funding behind those studies. When you bring something to FDA approval, okay, it is the company's or the manufacturer's responsibility to show that it is a safe and beneficial product, okay. They fund those studies. They don't get independent people to fund those.

Q. So they fund the studies, and do you have a problem with that?

A. No, I don't.

Q. Okay. So --

A. It's their product.

Q. And then publications come out over time?

A. It does inherently provide bias, potentially bias. Because if you invested millions and millions of dollars into a product and then it doesn't get FDA approval, then basically it's an investment that you've lost.

Q. So you're saying that all the investigators and individuals that have taught the skills and techniques of the product are biased?

MR. KOTT: Object to the form.

THE WITNESS: I did not say that. I said it does provide for bias. So that means it's going to potentiate, that is a possibility.

BY MS. MOORE:

Q. But investigators -- the authors on the various studies about the Prolift and the TVT and other mesh products, you're saying they are biased?

MR. KOTT: Object to the form.

THE WITNESS: You're inferring that. I did not say that.

BY MS. MOORE:

Q. You said bias?

A. I said it would potentiate the possibility.

Q. Okay. But I'm trying to understand in a study that's being conducted by doctors at various centers throughout the country and the world, you're suggesting that they could be influenced by bias?

MR. KOTT: Objection.

THE WITNESS: Again, you're inferring

that.

BY MS. MOORE:

Q. Help me understand.

MR. KOTT: Let him finish his answers, please.

THE WITNESS: When studies are designed, we as humans inherently there is bias. We all have bias from perspectives. We all bring that to the table with everything. Studies are designed to try and limit that: Can't do it completely, but they are designed to do that.

BY MS. MOORE:

Q. And --

A. I was just simply stating it potentiates the possibility of biases.

Q. And are you acknowledging that you may by biased in some of the work that you're currently doing now?

MR. KOTT: Object to the form.

THE WITNESS: As I may, so may be the experts that you use.

BY MS. MOORE:

Q. So it is a possibility?

A. Sure.

Q. And then --

A. But my bias is based on experience with the use of this product.

Q. I'm not limiting to that, but kind of the new work that you're doing that is being questioned by the scientific -- some people in the scientific arena. The work that you have done with the FAARN, is your work bias --

MR. KOTT: Object to form.

BY MS. MOORE:

Q. -- in your arena?

A. My work as it relates to the publication via the literature.

Q. I'm not talking about Manboob Nation. I'm talking about -- because that's one aspect of your work, the testosterone. I was talking about -- and maybe it's all related. I was talking about some of the other things that you're doing currently and some of your presentations.

A. I think you're misleading on the facts. That's just an organization that I pay a fee to.

Q. So you can speak?

A. No, no. It's just an organization I pay a fee, a membership.

Q. So you are a membership -- a member of that organization?

A. Yeah. But I don't do research for them and I don't do anything like that.

Q. Okay. All right. So back to my question. You did research last night to help supplement your opinion?

MR. KOTT: Object to the form.

THE WITNESS: I did a Google search.

BY MS. MOORE:

Q. Okay. I'm sorry. You did a Google search to help supplement the bases for your opinion?

MR. KOTT: Object to the form.

THE WITNESS: I did a Google search just to see if there's quickly something available out there, that any nonscientific person can just say, wow, is there anything possibly remotely out there to support it.

MS. MOORE: And do we want to go off record for a second and print that?

THE WITNESS: It's already printed.

MS. MOORE: You want to get that?

THE WITNESS: Sure.

VIDEOGRAPHER: You want to go off the

record?

MS. MOORE: Yes, please.

VIDEOGRAPHER: We are going off. The time is 8:28.

(Off the record.)

VIDEOGRAPHER: Okay. We are back on the record. The time is 8:34 a.m.

BY MS. MOORE:

Q. Okay. Let's see, Doctor. So we took a brief break and you handed me a copy of an abstract entitled "Transvaginal Repair Genital Prolapse: Preliminary Results of the New Tension-free Vaginal Mesh Prolift Technique, case series multicentric study." Looks like it was first online in November of 2006, correct?

A. Correct.

Q. And then the next two pages it says, "related articles containing similar context." What is that?

A. Just printed as part of the abstract, that commercial.

Q. And what was your search term?

A. Search term?

Q. Yes, sir.

A. This is based on my memory, but I would say it was Prolift, erosion rate. And I think that was it.

Q. Okay. Did you do a search for TVT?

A. I did not do a search for TVT.

Q. The statement in your consent that we have been focusing on of 3 to 5 percent is for Prolift or for Prolift and TVT? We really did not get into that.

A. I can't recall without looking at it.

Q. All right. We'll take a look at it. Now -- so let me make sure I understand. So the significance of this is that it shows you that there was literature out in the peer review -- strike that.

There was information available in the peer-review literature showing a similar revision (sic) rate to what you referenced?

A. No. I knew that material like that was also there. I was just showing you how readily available something was to quickly support and challenge what you were saying yesterday.

Q. All right. And so --

A. Because I knew information like this was

already available, thus I came up to 3 to 5 percent.

Q. I'm just trying to make sure I understand what we are -- you're trying to challenge that I was saying. This abstract supports -- stands for what? Why is this important to you?

A. Yesterday you were implying that there was no scientific evidence for the 3 to 5 percent that I was using in my consent, as I told you. It was employing the evidence available at the time in the literature, as well as guidance from the manufacturer of the product who, again, marketed as a revolutionary product. So, of course, they are going to be bringing (sic) it new and they need a resource to lean on. But you challenged --

MS. MOORE: Move to strike comments of Counsel -- or the answer.

MR. KOTT: He keeps answering your question.

MS. MOORE: Move to be strike comments. Non-responsive.

MR. KOTT: You can answer.

THE WITNESS: What I was simply doing was showing how readily available access to that research that I used to formulate that ratio

currently is through a simple Google search.
BY MS. MOORE:
Q. So there was literature in the -- strike that.
But there was -- literature was available that supported the rate that you used in your consent form?
MS. KOTT: No, it's not in the consent form.
BY MS. MOORE:
Q. I'm sorry the case --
MR. KOTT: Let's stop. Let's retract.
BY MS. MOORE:
Q. The literature was available that supported the 3 to 5 percent erosion rate that you have referenced?
A. That is correct.
MS. MOORE: Okay. Got it. Thank you. We'll go ahead and attach that.
(Exhibit No. 55 marked.)
BY MS. MOORE:
Q. But so I understand your experience was different, though. Your personal experience using the Prolift and the TVT was of erosion rate with the

15 to 20 percent?

A. Understand when you look at the volume of evidence that I had in my practice, though it was substantiated -- substantial comparatively to the volume of evidence, the power that was available through Ethicon, as a manufacturer of this product, it was much more powerful. And thus as you analyzed data, the power of that has to be taken into context with the limited power of my personal. So if I had gone on and done more, or say, doubled what I had done and their claims about the safety and the erosion rate of the product were as they claimed, then I simply could have had zero the remaining aspects of my surgical procedures. However, I think evidence and history points to just the opposite.

Q. Move to strike. Non-responsive.

The question that I asked is, what was your experience, your erosion rate?

A. I quoted you that my experience rate was 15 to 20 percent erosion rate.

Q. And -- so you are a member of the 4AR committee, organization?

A. A4M.

Q. Sorry.

A. Correct.
Q. Correct?
A. Yeah, correct.
Q. And I believe you testified you're aware that the organization is not recognized by the American Medical Association?
A. And I think I said yesterday I recognize that.
Q. And that many of the recommended treatments, such as hormone treatment, do not have support from a consensus of the scientific and medical community?
A. Well, it's referenced in my book. What I wrote was that as it relates to testosterone, the majority of the literature actually contradicts what is in traditional medical -- in a traditional medical practice. So just because I'm a member of that organization does not mean I full -- I support any and everything that they do just as if I'm a member of ACOG.
Q. You are a member of ACOG now?
A. I am.
Q. It's not on your CV?
A. Is it not?

Q. No.
A. Okay. Sorry.
Q. Because I asked you yesterday and you said that you were not.
MR. KOTT: Object to that.
THE WITNESS: You did not ask if I was a member of ACOG.
BY MS. MOORE:
Q. I'll tell you how I asked, I asked if you were a member of any of the professional societies, and you said no.
A. Then that slipped. I am a member of ACOG.
Q. I'm looking at your two-page CV, right? This is it, two pages?
A. Yeah, that's what I gave you yesterday. Actually, it may be three. But, okay.
Q. If there's another page, I want to see it.
A. If that's what you got, that's what I gave you so --
Q. All right. And --
A. I've always been a member of ACOG. I have to be a member of ACOG. I just missed that.
Q. Okay. Do you --
A. When you referenced that question, I

thought you were talking SGS, AUGS, etcetera.

Q. Move to strike. Non-responsive.

Did you -- have you published on any issues that were -- any gynecological issues?

A. I have not.

Q. You have not submitted any peer-review paper on any -- any papers to peer-review journals on obstructives in gynecology?

A. Obstructives?

Q. Obstetrics.

A. Obstetrics? No, I have not.

Q. Not obstructives. I don't know, have you done that?

A. No. I don't think there's anywhere to publish that.

Q. Yes. That would be definitely very interesting. And, of course, you haven't prepared any books or manuscripts in that area, correct?

A. Correct.

Q. Where are your notes from the preparation of the reports?

A. My notes for the preparation of the reports?

MR. KOTT: Object to the form.

THE WITNESS: I don't have notes. I have maybe edits.

BY MS. MOORE:

Q. Where are your edits?

A. I have them on file in my computer.

Q. So you -- the only notes that you have would be the edits that you made to your report?

MR. KOTT: Object to the form.

THE WITNESS: That's how I write.

BY MS. MOORE:

Q. I'm trying to understand when you were preparing the reports, how did you go about doing that?

A. Well, it's a review of the literature, as I put there. And it's a formulation of my opinions as I write it.

Q. And did you take any notes when you were looking at the medical records? How did you remember all the medical records and all the dates and the treatments?

A. Well, the dates and the treatments, those are in the medical records.

Q. Did you highlight the medical records?

A. I had it in front of me, and so I would

read it.

Q. And then -- so you have no notes or no highlighted information, you were just able to do all this?

A. I had my laptop here, I had the medical records here. I pull it there. I write. Pull it. Write. So I wasn't taking notes as you would describe it. That's not the way I write.

Q. Okay. And throughout the entire practice of working on the four reports, you did not take any notes?

A. I don't recall taking notes, as you described them. I told you how I structured that process.

Q. So you would just pull -- review records and pull what you needed, and type it into your report?

A. That's how I write.

Q. So the record is clear, you have no notes?

A. I told you I have edits of my opinions.

Q. What are your opinions on the flu vaccine?

MR. KOTT: Object to the form. Relevance.

THE WITNESS: Well, what do you want to know about it?

BY MS. MOORE:

Q. Do you think that the evidence supports -- the scientific evidence supports the vaccine?

MR. KOTT: Object.

THE WITNESS: I think when you look at the evidence of the literature, okay, Cochrane Review, time and time again, and I have that published at length to that, the evidence and their conclusions is when you're looking at the transmission rate of the flu vaccine, it does not prevent transmission, number one.

Number two, does the flu vaccine prevent secondary complications such as pneumonia? The answer based on the literature review, via Cochrane Review multiple times, is no. So in some contexts the flu vaccine is not the best option. There are others where it is.

BY MS. MOORE:

Q. So the CDC says everyone over six months should get a flu shot, correct?

MR. KOTT: Object to the form. Object to the assertion.

THE WITNESS: That is correct what it says.

BY MS. MOORE:

Q. Do you disagree with the CDC? Center for Disease Control.

A. I'm saying what the scientific literature shows.

Q. Well, I'm asking your opinion versus the Center for Disease Control, CDC, Doctor.

A. My opinion is guided by the volume of evidence of the literature.

Q. So your opinion is at odds with the CDC?

A. As a lot of physicians can disagree --

Q. Absolutely.

A. -- experts can disagree. I disagree with their broad bases of it. As I stated earlier, there are some indications for it, and there are some not indications for it.

Q. But for the opinion that everyone over six months should get a flu shot, do you agree with that CDC statement -- I'm sorry. Strike that.

You disagree with that CDC statement?

A. As I told you, in select cases the evidence does not show it, and I referenced those Cochrane Reviews that support it.

Q. And you have published on that. Where is

the publication?

A. Published?

Q. You said something about I have a publication?

A. I wrote a blog.

Q. What else have you written blogs on?

A. Written blogs on hormones. On nutrition. On exercise.

Q. Things that are current to your focus today?

A. Correct. Since I made the change based on my experience with the product.

Q. Since you made the change based on your experience with the product, what does that mean?

A. That as I discussed yesterday, with the new product and the teachings -- the new product as it came to market, the confidence in those products, as I told you before, I lost confidence in the information that was presented about the safety and efficacy of the product. And that over time as my erosion rates and complication rates began to be published in the literature and supported what I was finding and not what was being told to me, I stopped pelvic organ prolapse, urinary incontinence

surgeries because of that. And made the change outside of that type of practice.

Q. When did you fist start having some concerns with the TVT or the Prolift?

A. To give you a date of when I first started having concerns, I can't give you a date.

Q. Can you give me a range? Was it 2005, 2006, 2007, 2008?

A. I'd say 2008. 2008.

Q. So around 2008 -- before 2008, you did not have any questions? Because I thought in 2007 you were questioning at the round table --

A. No. That actually -- I was incorrect on that. The date is actually 2008.

Q. That's in 2008?

A. Yeah. That was not 2007, that was 2008. They would have those every year and that was a 2008 conference.

Q. When did you remember that?

A. Last night.

Q. So what else did you remember last night?

A. That in 2009 there was a conference and I was sick and I did not go to it. And that in 2008 Ethicon paid for us to go skiing when we were up in

Utah. They had us for cocktails. I saw the Jonas Brothers in the lobby of the American.

Q. Did your daughter like that?

A. And I got a signature so.... and they were very cool so.... you know, so those are the things that I remember.

Q. All right. So last night did you do any research on this?

A. No.

Q. But you remembered that the round table was in 2008?

A. Yes.

Q. Was the round table also in 2007? Was there another similar-type conference in 2007 or 2006 was that held every year?

A. These were annual events that they would have. Because, like I said, there was one in 2009 that I was unable to attend.

Q. Okay. So did you go to the one in 2006?

A. No.

Q. You did not?

A. I don't recall going, no.

Q. Did you go to the one in 2007?

A. As I said, no.

Q. So how do you know that you went to the one in 2008?

A. Because I asked Mikalia and she sent me an email referencing some emails.

Q. Okay. Where are the emails?

A. They are emails that were sent to me this morning.

MS. KOTT: I've got them. These are your documents that I just looked at last night based on where your questions were going.

BY MS. MOORE:

Q. So you asked her to help you find some things?

MR. KOTT: Object to the form.

THE WITNESS: No. This was months ago when we were discussing on the timeline of this conference, and I had referenced 2007. And I guess she just -- she sent me an email this morning said, hey, here's some documents that the defense attorneys -- that actually say 2008.

BY MS. MOORE:

Q. I'm going to move to strike. That is wholly inappropriate for you to be having

information fed to you by your lawyers in the midst of a deposition, and now you're changing your testimony. I'm going to move to strike any reference to information that you're asking people to help you find to go back and change your testimony.

A. You're implying that I asked, I did not ask.

Q. Whether you asked or received, you're referencing it now, and that is inappropriate, sir.

MR. KOTT: Hold on a second. Let me know when you're finished, please.

MS. MOORE: I'm finished.

MR. KOTT: Okay. There's nothing that's been done in this deposition and last night or days before. I believe what the Doctor is referencing is that there was communications that the defendant asked us to pull up last night, emails, that contained information that indicated the meeting was in 2008. I'm finished with that.

I object strongly to the comments that Counsel is putting on this record, that something is inappropriate, that you can't talk

to your expert in between separate depositions about separate clients.

BY MS. MOORE:

Q. Your testimony yesterday throughout a very, not one deposition, but two, and very detailed questions was about a 2007 time period and six months before that. And now you're changing that. Do you have any other mysterious sales reps that have appeared last night?

MR. KOTT: I'm sorry, could you repeat the question?

MS. MOORE: Absolutely. Could you repeat the question?

(Requested portion read.)

MR. KOTT: Object to the form of the question. And I'll put on the record, the best evidence of when this meeting took place and what time that this doctor attended, it would be in the hands of the defendant if they kept their records accurately.

MS. MOORE: Move to strike comments of Counsel.

BY MS. MOORE:

Q. Sir, why did you bring that up today?

A. Why did I bring up what?
Q. Why did you try to rectify your testimony from yesterday?
MR. KOTT: Object to the form.
BY MS. MOORE:
Q. Was that important to you?
A. You asked me another question.
Q. Yes, I am.
A. No, you asked me a first question and had her read it back.
Q. I'm moving on to another question.
A. Okay.
Q. Why is it important to rectify your testimony from yesterday?
MR. KOTT: Object to the form.
THE WITNESS: I wasn't showing a need to rectify.
BY MS. MOORE:
Q. Okay. So why did you --
MR. KOTT: Object to the form. He's not finished his answer.
THE WITNESS: I was confident in the numbers that I quoted you.

BY MS. MOORE:

Q. Okay.

A. And I was just showing you how readily available that information was.

Q. I'm not talking about the research that you did last night.

A. Okay.

Q. I'm talking about the fact that you received emails from your Counsel this morning --

A. You asked for all information related to our emails and this was --

Q. And you selected one thing that you're going to refer to today?

MR. KOTT: Object to the form.

THE WITNESS: We gave you all the emails.

MS. MOORE: I don't have any emails.

MR. KOTT: Just hand her the emails. This is ridiculous. There, there's your emails.

BY MS. MOORE:

Q. We'll go through those at a break. Now, anything else that has come to you that you would like to change in your testimony?

MR. KOTT: Object to the form.

MS. KOTT: This is the email he's talking

about.

THE WITNESS: Not as it relates to my testimony, no.

BY MS. MOORE:

Q. Okay. Let's see. So -- now, let me just make sure I understand. When did you have erosion rates of 15 to 20 percent? Was it in -- now it's 2008 -- not until 2008 -- everything looked good until 2008?

MR. KOTT: Object to the form.

THE WITNESS: You're asking me for a review of -- from 2016 to that time frame, and I'm giving you a range of time as I referenced initially 2007 as a reference to that conference. And that conference was actually in 2008, the one that I attended. And so as I referenced the speaker, referencing a 1 percent erosion rate, and my conversation with my colleague to my left, that that was a difference.

So when you asked me to identify a time point, though that's hard to identify a time pointed, because I never sat down and said, aha, I have 15 to 20 percent. Okay. I was

giving you a range of when I started to look at my rates compared to what was published and what I feel to be not correct publication of that material by Ethicon.

BY MS. MOORE:

Q. And were your erosion rates correct?

A. Were my erosion rates?

Q. Correct.

A. Well, at that time Ethicon was promoting a 1 percent erosion rate per the expert.

Q. I'm talking about yours.

A. My erosion rates had actually turned out to be what is supported in the literature currently.

Q. So they were lower?

A. No, I didn't say that. I said -- you're asking -- what I quoted was 3 to 5 percent, which was guided by Ethicon in the literature available at the time.

Q. Okay.

MR. KOTT: Please quit interrupting the witness.

BY MS. MOORE:

Q. I apologize.

A. And I told you my erosion rate was 15 to

20 percent.

MR. KOTT: Wait a second. Object to commentary on the record.

THE WITNESS: So you have questioned why I didn't counsel patients on the high erosion. My erosion rate actually is what is turning out to be supported in the literature currently. Which, by the way, has resulted in the pulling of the product in 2012. And thus my erosion rate was much higher and my suspicions which finally proved to bear out contrary to what was published by Ethicon.

BY MS. MOORE:

Q. Move to strike as non-responsive.

Your erosion rates were in -- let's say in the 2006, 2007, 2008 period, what were your erosion rates?

A. Can you re-ask that question?

Q. Sure. During the 2005 to 2008 time period, what were your erosion rates?

A. At that point, to be honest with you, I can't say that I could tell you a percentage of erosion rates.

Q. So -- okay.

A. You have asked me to estimate it based on what I started to question what was being promoted.

Q. And when did you -- okay.

When did you start to question what was being --

A. As I told you earlier, at that conference.

Q. That's the first you hit it -- you --

A. When I started to question and formulate questions in my mind.

Q. -- was in 2008?

A. Yes.

Q. Okay. So prior to 2008, there was nothing that concerned you?

A. I don't recall. You know, this is a new product. I had no reason to -- I trusted Ethicon and their teachings and their publications on that material that this was a safe and effective product.

Q. And your experience up until 2008 -- when was the conference?

A. It was in the winter, because they took us skiing.

Q. Okay. So this is -- it looks like the -- it doesn't specify when the conference is, but the emails are in March of 2008?

A. Yeah. Spring skiing.

Q. So --

A. We went skiing.

Q. So sometime you were skiing, and it was on that trip or right before that trip that you started having concerns about your erosion rate?

A. As I've mentioned repetitively, is that at the round table is where they were quoting very, very low erosion rates, of which I was not seeing, of which I would then speak to a colleague on my left and they would verify they were not seeing the same erosion rates. That process started. I started to question.

Q. But the erosion rates that were being discussed by the Ethicon presenter were not the type of erosion rates that you were seeing, you said it was around the 15 to 20 percent?

A. When I started to formulate that question, when you asked me for a date and a percentage, that's what I told you, yes.

Q. It was around --

A. Fifteen to 20 percent.

Q. -- 15 to 20 percent. And, let's see -- so what did you do with your concerns? Did you express

them to Ethicon?

A. I -- excuse me, I expressed them when I returned to my practice, to my rep when he showed up in my office.

Q. Other than -- and have you had a chance to remember the rep's name?

A. No. I told you I don't remember his name.

Q. Do you remember anything at all about the rep?

A. As I told you yesterday, I don't remember anything at all about the rep. But it is very, very normal for Ethicon to have reps, for every company to have reps. They would visit me all the time. Bard, AMS, pharmaceutical reps would come in all the time. But that doesn't mean I remember their hair, their skin color, their name, their background, their family tree, etcetera.

Q. Move to strike as non-responsiveness.

So you approached the sales rep on one occasion, several occasions? Were you upset, frustrated, what did you do?

A. No, usually when he came into the OR.

Q. And he came in the OR and you said, I'm not seeing your erosion rates that you're telling

me?

A. That's correct.

Q. What did he say?

A. So, obviously, when that happens, you go, well, could it be my limited experience in my volume and then maybe I just don't have the power that matches their power. So is that possible. Is it because they are an expert and I am an expert, but as a gynecologist. And the response was, no, we bring physicians to you to train. So we would not do that if we did not feel you had the skill set and the proper technique to provide a good placement of the mesh and management of these clients.

Q. So you had that one conversation with him. Did you have any other conversations?

MR. KOTT: On any topic?

BY MS. MOORE:

Q. No. About his concerns with the products. I mean, with the erosion or with the Prolift or the TVT.

A. To say do I remember a specific conversation, there would be multiple conversations as it relates to other reps come in about -- with competing products and their claims on erosion and

complication rates. And we would contrast -- I would ask him to contrast that with the evidence that I had, as well as the company Ethicon said. So we would have those conversations. But I don't remember the specifics of these conversations.

Q. Did you ever bring it -- strike that.

Did you ever go beyond the sales rep and contact anyone at Ethicon say, hey, I'm concerned, I'm seeing higher erosion rates than what you're telling me?

A. The rep's role is to be the interceder between the physician and the company. And so when I gave him that information, it was for him to relay that up. It was not intended for coffee talk.

Q. Okay. And so you said reps. I want to make sure, now there's several reps involved?

A. I said rep. You may have heard reps. I said rep. If I said reps it was a misspeak. But that is what reps to do.

Q. There's one rep that we are referencing that you were having these discussions with?

A. Correct.

Q. All right. And the discussions started when?

A. Every time he would come and see me, we would have discussions.

Q. About your concerns?

A. No, about discussions in general.

Q. All right. So the record is clear, I'm talking about discussions that you may have had with the rep, that you can't recall, about concerns with the Prolift or the TVT. Specifically we'll stay with the erosion.

A. As I mentioned, when I came back from that conference, that was when I distinctly remember a conversation that entailed the quoted erosion rate by the speaker. And my erosion rate of which I was seeing that were exceeding that, as well as the published, i.e., 3 to 5 percent range.

Q. And you had discussions with him and he basically told you that --

A. When I had discussions with him about this or anything in the matter, it was to relay it. So, for example, when there was discussions about the trip to go to Utah, you know, he asked me if I wanted to go skiing. I said, I'd be happy to get on that bus. He relayed that information on up. So that's exactly what happens. I expected that

information to be relayed up, so as any information that needed to clarify would be relayed down.

Q. Okay. How concerned were you? I mean, did you have several conversations with him or just one?

A. To be honest, I don't recall the number.

Q. So did you -- did your concerns go away? Were you suddenly fine and just --

MR. KOTT: Object.

BY MS. MOORE:

Q. I'm trying to understand. At some point before the conference in 2008, you came to the conclusion that your erosion rates were around 15 to 20 percent?

A. As I told you before, I started to formulate the idea that my erosion rates were exceeding that and you asked me to quote a percentage, and that's what I quoted you as an estimate, and I did. And I said that started the formulation in my idea that this product was not safe and effective as described. And that process of change allowed me to build confidence, and it took time, where I eventually stopped doing this product. Prior to its elimination from the market,

by the way.

Q. Move to strike from elimination from the market on as non-responsive.

Now, you started having concerns about the product not being safe, correct?

A. Correct.

Q. And when did you start having those concerns?

MR. KOTT: Object. Asked and answered.

THE WITNESS: Yeah. As I told you, the process started when I was seeing quotes from other surgeons that were outside the realm of what I was seeing. One percent.

BY MS. MOORE:

Q. Lower than what you were seeing?

A. Exactly.

Q. Did you question your technique?

A. Any good surgeon would do so.

Q. Okay. And you did?

A. Correct.

Q. And I did note in all of the reports that you have prepared in this litigation, you have exonerated your technique, correct?

A. I didn't exonerate. When the rep was in

the operating room with me, I asked him if my technique was an issue, number one.

Number two, Ethicon saw me as a person to train others to do it. And they called me a master consultant, number two.

Number three, when I asked him that, he would tell me that, "Look, we have physicians that come to you, to watch you, not only in Celebration, but also here in the operating room in Louisiana to learn how to do the procedure. So, no, there's not a technique issue." So that provided confirmation to me that Ethicon felt I had the surgical capability and expertise to be able to perform the surgery well, and teach others.

Q. I'm not talking about anything but the four cases before us. And is it your opinion, as an expert, that the -- that you as the implanter did nothing wrong?

A. I followed the procedure guidelines and teachings that Ethicon provided.

Q. And so to answer my question, you were serving as an expert in this case, and in that capacity you have done your differential diagnosis, including looking at the implanter, who happens to

be you, your technique, and said, there's nothing wrong with that technique?

A. I provided the technique that Ethicon taught me.

Q. And did you do everything that Ethicon taught you?

A. Well, as it relates to the technique of prolaft -- Prolift, excuse me. They were the author of that technique. So as they trained me, I did provide that.

Q. Did you not provide any medical judgment or skill from yourself, or are you just like a robot doing whatever Ethicon tells you?

MR. KOTT: Object the form.

THE WITNESS: Of course I do.

BY MS. MOORE:

Q. That's what I'm trying to understand.

A. But you did not ask that.

Q. Let's ask that. Did you provide any skill and technique, or do you bring anything to the table or do you solely rely on what Ethicon tells you?

A. The technique is the steps involved. That's what Ethicon provided. Okay. I provided the hands, correct. The hands for which I was named the

top surgeon in my residency class. For which Ethicon saw as valuable.

Q. How many years ago is that?

MR. KOTT: Don't interrupt him, please.

THE WITNESS: For which Ethicon saw value in teaching other physicians in Celebration, Florida, as well as bringing physicians in to teach. So they obviously saw the value there. Others obviously saw the value in my hands. So if you're questioning my hands, I think Ethicon's choice of my hands as a surgical example I think basically bears that out.

BY MS. MOORE:

Q. And in these four cases that you have reviewed as the expert, looking at your work as a treater -- you're playing dual roles here, right?

A. I understand that.

Q. You're sitting in a position where you're judging what has taken place with these cases, and part of your judgment includes looking at what you, yourself, did as a doctor treating one of the patients?

A. That's correct.

Q. And you have checked that box and said,

what I did was perfectly fine?

A. What I knew available at the time of the evidence, yes. But as I've mentioned beyond that yesterday, is if I had available evidence now, I would have never implanted those materials, because of the evidence bearing out that these were not safe products.

Q. Okay. And when did you first start -- getting concerned about the safety of the product?

MR. KOTT: Object to the form. Asked and answered repetitively.

THE WITNESS: I think I've answered that several times.

BY MS. MOORE:

Q. I need you to answer, please.

A. Okay. The meeting in Salt Lake City where the quote on the complications of the mesh erosion that was quoted as being below what the -- what the published literature was showing, okay, the 1 percent that was being quoted. And beyond what -- not what was just published, but beyond what I was seeing, started to formulate the questions and started the process of challenging my belief that the product was safe and effective.

Q. Okay. And so up until that time period you started -- I guess if you -- strike that.

At this meeting, you had concerns about what you were hearing from Ethicon about revision rates based on your experience?

A. That is correct.

Q. And your experience was a higher revision rate?

A. Higher erosion rate reference.

Q. I'm sorry.

MR. KOTT: That's okay, it gets confusing.

BY MS. MOORE:

Q. It was an erosion rate?

A. Correct. Erosions will lead to revisions.

Q. Thank you.

MR. KOTT: Can we take a break, we have been at it about an hour?

MS. MOORE: Sure.

VIDEOGRAPHER: Going off the record. The time is 9:13.

(Off the record.)

VIDEOGRAPHER: Okay. We are back on the record. The time is 9:23 a.m.

BY MS. MOORE:

Q. All right, Doctor. I think we were kind of working through some issues. I asked to -- what you did last night. You told us about some of the research you did. You talked about the emails. And now I want to make sure is there anything else, any additional information you have, any way you want to change your testimony from yesterday?

MR. KOTT: Object to the form.

THE WITNESS: Uh-uh.

BY MS. MOORE:

Q. You stand by what you said?

A. I was providing clarification. You asked if I did anything, and so I told you.

Q. And your testimony yesterday was truthful and accurate?

A. Yeah, 3 to 5 percent as I quoted and I supported that today.

Q. Supported the 3 to 5 percent with what you were seeing -- what was also available in the literature?

A. Correct.

Q. And so during this time period, though, you started getting more and more concerned with the

products, meaning the Prolift and the TVT?

MR. KOTT: Object to the form. Vague.

THE WITNESS: I was concerned about the efficacy and safety, as was being -- the information as it was being provided by the company, yes.

BY MS. MOORE:

Q. And so you approached the sales rep and was -- did you ever hear back?

A. Again, you're asking me to recall specific conversations. I can remember generalizations, but I don't recall any response back.

Q. And so did that trouble you?

A. Well, obviously, this was a process of formulation. And so I was formulating opinion. If I would say troubling, the continued ongoing complication rates were troubling. And that, again, eventually led to my cessation of these procedures.

Q. And so all this started around the 2008 period, a little before you started recognizing your erosion rates were higher than what you were being told by Ethicon? And that continued -- that concern continued through 2008, 2009, 2010?

MR. KOTT: Object to the form.

THE WITNESS: Again, when you asked me to try to narrow down a time frame, I'm giving you a time frame period as best I can based on history recollection from eight to ten years ago.

BY MS. MOORE:

Q. Right. And so the best reference point you have is the meeting that you attended in -- the skiing trip you attended in -- where is -- Salt Lake City?

MR. KOTT: Object to the form.

THE WITNESS: Yeah. They not only paid us an honorarium, they paid for our expenses up there. This was at the American in Salt Lake City and they were in round tables dealing with the complications. Dinners, cocktails, and they took us skiing.

BY MS. MOORE:

Q. All right. And you enjoyed that?

A. Well, yeah.

Q. And it was during this time period, though, that you started having concerns about the safety --

MR. KOTT: Jesus.

BY MS. MOORE:

Q. -- of Prolift and TVT?

MR. KOTT: Object the form.

THE WITNESS: Again, you're identifying when I maybe noticed a difference that concerned me. And that is in my mind a point that is significant.

BY MS. MOORE:

Q. Okay. So at least that's the time point we know you started having some concerns, correct?

A. That is correct.

Q. And then that would have continued until the time you stopped using the product?

A. That is correct.

Q. When I say the product, I mean the TVT and the Prolift.

A. Correct.

Q. Okay. And so during this time period, you continued to teach people on techniques of the TVT and the Prolift?

MR. KOTT: Object to the form. Vague.

BY MS. MOORE:

Q. Meaning after the 2008 time period.

A. I believe that my last contract was in

2009, but then at that point I decided not to continue that process.

Q. So you accepted money and signed a contract dated January 2009 to be a consultant for Ethicon on the Prolift, despite the fact that you had concerns about the safety and efficacy of the product?

MR. KOTT: Object to the form.

THE WITNESS: I told you I was processing the concerns about the product. But as you know beyond 2009, I did not.

BY MS. MOORE:

Q. So it was okay for you to accept money from the company while you were having concerns about the safety and efficacy of the product?

MR. KOTT: Object. Form.

THE WITNESS: I was still formulating my opinion at that point. And, obviously, Ethicon still felt that I was a valuable surgeon in that aspect.

BY MS. MOORE:

Q. Move to strike anything about what Ethicon thought.

My question is, during this time when

you're talking about concerns, it was okay for you to continue to accept Ethicon payments?

MR. KOTT: Object to the form.

THE WITNESS: At that point I did not come to a formulated final decision, and when I did, I stopped.

BY MS. MOORE:

Q. When did you do your last Prolift surgery?

A. I don't recall when I did my last.

Q. You have no recollection?

A. No, you don't. It's -- as a surgeon you don't bandy that stuff around. You don't put that on a wall or something.

Q. When did you do your last TVT surgery?

A. Again, I don't recall.

Q. Okay. But in 2009 you did accept money from Ethicon to be a consultant and teach in Florida, you taught the Prolift?

A. I don't believe I taught the Prolift in Florida in 2009.

Q. So you just accepted the money, but you did not teach --

MR. KOTT: Object to the form.

THE WITNESS: I just have what's right

there.

BY MS. MOORE:

Q. Okay. We'll go ahead and --

A. Yeah, I'm sorry, I thought I turned it off.

Q. You want to go off record? You need to take that?

A. No, I just need to turn it off. Sorry.

MS. MOORE: We'll go ahead, and -- I think this has been marked as the individual one, 2009 has been marked?

MR. KOTT: The whole package has been submitted.

MS. MOORE: I'm going to pull this one out, since it's unique to 2009, and go ahead and mark that as Exhibit No. 56.

(Exhibit No. 56 marked.)

BY MS. MOORE:

Q. Did Ethicon approach you in 2010 to serve as a consultant?

A. I don't recall.

Q. All you know is that you served as a consultant, received payment for doing that in 2009 while having concerns about Prolift and TVT?

MR. KOTT: Object to the form.

THE WITNESS: Yeah, I think that you see that there.

BY MS. MOORE:

Q. Let's see.

A. Excuse me.

Q. You want to turn to Tina Morrow, your report that we have previously marked as --

MR. KOTT: They have one.

THE WITNESS: Okay.

(Exhibit No. 53 marked.)

BY MS. MOORE:

Q. Yeah, No. 53. Did you all bring a report with you today?

A. I have it on my computer.

MR. KOTT: We have a copy somewhere.

BY MS. MOORE:

Q. Here you go.

A. Try to stay digital.

Q. Now -- and your reliance list, you probably want to have -- thank you. We marked the reliance list as Exhibit No. 54. Just take a moment. Go off record, take a moment and have a look at your report.

(Exhibit No. 54 marked.)
VIDEOGRAPHER: Going off. The time is 9:31.
(Off the record.)
MS. MOORE: All right. We are back on the record.
VIDEOGRAPHER: We are.
BY MS. MOORE:
Q. All right. And looking at your report in the Morrow case, and your background section is similar to reports that we have discussed previously; is that fair to say?
A. Correct. It's exactly the same in the other reports.
Q. Let's turn to the first time you had an opportunity to see her. And my records indicate June -- June 11th, 2008?
A. Yeah, just have my report in front of me.
Q. Did you bring the records today that we requested?
MR. KOTT: They have been produced multiple times. Do we have a copy --
MS. MOORE: Let's go off the record for a second.

VIDEOGRAPHER: We are going off the record. The time is 9:34.

(Off the record.)

VIDEOGRAPHER: We are back on the record. The time is 9:37.

(Exhibit No. 57 marked.)

BY MS. MOORE:

Q. So, Doctor, you have in front of you what has been marked as Exhibit No. 57. It's the records that you have produced through your Counsel for the client here, Mrs. Morrow?

A. Correct.

Q. And are there any communications referenced in there, emails, documents, to Mrs. Morrow?

A. I think I referenced yesterday, communications I had with patients would be face to face.

Q. Let's go to the first visit, June 11th, 2008. And let's talk about the complaints she had on that particular visit. And the records I have are that she had joint pain, fatigue, migraines, and difficulty sleeping?

A. Well, I have a little bit more than that.

Q. Okay. Please.
A. Joint aches, dry skin, fatigue --
(Reporter clarification.)
THE WITNESS: I'm sorry. Joint aches, dry skin, fatigue, memory impairment, sore muscles, poor appetite, weakness, weight gain, bloating. Incontinence she described as stress and urgency influenced. Dry skin, as I mentioned. Headaches. And sleep disturbance.
BY MS. MOORE:
Q. Anything else?
A. No, I think that sums that up.
Q. And her weight at the time?
A. Her weight --
Q. I have 269 with a BMI of 41.8?
A. I think that's a five. But I think it's 259.
Q. Whatever you say, Doctor.
A. Yeah, the BMI would be correct, because that would incorporate that weight.
Q. And then let's go to your physical exam. You did genitourinary. And looks like you found a cystocele, rectocele, enterocele; is that correct?
A. Yeah, that's how it reads, correct.

Q. And then it says "pelvic enterocele," what does that mean? That's further down.

A. That's just a CPT code.

Q. Okay. And this also -- why don't we get your expert report in front of you.

A. Got it right here.

Q. You have captured that in your expert report about the patient presenting for menopausal symptoms and hyperthyroidism. And then you capture cystocele, rectocele, enterocele, and I guess you did an examination. And then I guess you did the POP Quantification on that date as well?

A. Actually, if you look back in the plan for recommendations and also in the plan it says "schedule POP-Q."

Q. Okay. Your report -- for clarification, look at your report, and it says that a stage two cystocele, rectocele, and enterocele were found on examination?

A. Uh-huh. Yes.

Q. And were they found -- they weren't found on June 11th, '08, they were found on a subsequent examination?

A. Well, just when you see somebody with

prolapse, when you have done enough prolapse exams, you have a very good -- when you have done enough of them and become an expert, you have a good idea of what a range is going to be of their prolapse based on their symptoms. Again, stage one and stage two are really clearly identifiable. It's the stage three and stage four that become a little bit more difficult to quantify. So you have a good idea on most stage twos where they are, although a POP-Q is scientifically recommended really to quantify to follow.

Q. All right. What is a spit test?

A. I don't know. Where do you see that?

Q. Did you -- Ashley Moore worked for you at one point, or Mrs. Moore's daughter?

A. She was the receptionist.

Q. Okay. And she referenced you doing a new test, a spit test?

A. Who did?

Q. Mrs. Moore was referencing what you were doing. Did you do a spit test at your office?

A. Well, there's a wide variety of test mediums, and saliva is one of them, that is correct.

Q. Are they known as spit tests?

A. I guess you could say that that's how you did it, yeah, you spit or drool.

Q. And what do the spit or drool tests show you?

A. They can show you a variety of things. They can show you cancer markers. They can show you hormones. They can show you inflammatory markers. They can show bacterial content of the mouth.

Q. All right. So let's go further down. It looks like you did some testing, urodynamics and cystoscopy. And based on those studies, there was a diagnosis of mixed urinary incontinence that's referenced in your expert report; does that sound about right?

A. Correct. As matched via her complaint when she came in.

Q. Okay. Let's go to the next visit, July 3rd, 2008, an office note.

A. July 3rd?

Q. That's what I have. July 3rd, 2008.

A. Okay, sorry. Yes, I have that.

Q. And did she have any complaints on that date?

A. Again, when you look at a review of

symptoms, they are as she was when she came in, which was the abdominal bloating, urinary incontinence. Both she described as stress but also urgency induced.

Q. All right. But no other complaints other than those contained in the review of symptoms?

A. That is correct. Or in her HPI.

Q. Right. And just any complaint -- what's complained in her HPI, tell me what's in the HPI.

A. Right. About history, present illness.

Q. And what are the complaints?

A. It's as I read before, you want me to reread those?

Q. I'm trying to understand the July 3rd, 2008 visit, was there any specific complaints that she referenced that day?

A. Yeah. As I referenced related to -- you asked me -- did she have any complaints related to her pelvis. And I referenced in her review of symptoms, she gave the same at that visit as she did on the initial visit.

Q. And that would have been the bloating --

A. The bloating, the urinary incontinence, stress but also urgency associated.

Q. She was taking Estrace at that time three times a week?

A. Where do you see that?

Q. The Estrace is going to be under your prescription.

A. That is on July 3rd. When I look at prescriptions on that date, I see Levothroid and APPI or Ranitidine.

Q. All right. I'm looking at --

A. That's July 3rd.

Q. I am looking at July 3rd, and if you go to the one -- the fourth page back up -- let me give an example --

A. I prescribed it that day. Thank you. I was looking at her history of medicine. Her medicine she had that day. Yes, correct. Okay.

Q. And my question was, why were you prescribing the Estrace?

A. Atrophic vaginitis, although I did not comment, here can be common contribution to urinary incontinence. So a conservative approach to urinary incontinence would employ, at least in part, vaginal estrogen to strengthen the vaginal mucosa.

Q. And diagnosis, it looks like pelvic

enterocele. That's a small bowel prolapse?

A. Again, these are CPT codes and these CPT codes have numerous different descriptions attached to them. That's just the one that happened to pop up. But, yes, an enterocele is an upper large intestine prolapse, or it could be small intestine into the vaginal vault.

Q. All right. Let's go through the risks you discussed with her on that date. So at this point you're July 3rd, you're talking to her about surgery; is that right?

A. That is correct.

Q. And you're telling her the pre-op plan. And, again, the risks discussed include infection, hemorrhage, blood clot, transfusion, 3 to 5 erosion risk, failure for reconstructive support, damage to bowel or bladder, incidental oophorectomy. Now, that's a new one, we did not see that in what we discussed yesterday.

MR. KOTT: Object to the form.

BY MS. MOORE:

Q. Incidental oophorectomy, extrusion graft, graft infection, death, conversion to laparotomy, de novo urinary irritative voiding symptoms, VTE.

Are those the risks you discussed with her?

A. Yeah, as you've listed there and read all.

Q. All right. I'll find it and attach it. I'm going to ask you to look at the -- the risks that you read yesterday to Ms. Taylor in August of '08. So that would be a month later. And I just wonder why different risks for different people. Was a sales rep involved in altering the form at this point?

MR. KOTT: Object to the question.

BY MS. MOORE:

Q. Please take a look at this. I'm going to look -- find the exhibit number in a minute.

MS. KOTT: You want a mic?

MR. KOTT: I think this is picking up.

MS. MOORE: Let's go off the record for a second.

VIDEOGRAPHER: We are going off the record. The time is 9:48.

(Off the record.)

(Exhibit No. 58 marked.)

VIDEOGRAPHER: We are back on the record. The time is 9:54.

BY MS. MOORE:

Q. All right, Doctor. Took a quick break so that we could identify what we have previously referenced as a consent discussion with another one of your patients, Ms. Charlene Taylor. That exhibit is labeled as Exhibit No. 58. And I wanted you to take a moment and compare the consent discussion you had with Ms. Taylor in August of 2008 with the consent discussion you're having with Mrs. Morrow in -- three months earlier, July of 2008.

A. Okay. I don't have that.

MR. KOTT: He needs a copy. It would help.

THE WITNESS: Okay. So you want me to read the two --

BY MS. MOORE:

Q. I'll make it easier for you, if -- the Taylor discussion references failure urinary retention, at the end, I believe.

A. Yes.

Q. Pardon?

A. Yes.

Q. So you have that in one consent, but you don't have that in the consent for Mrs. Morrow?

MR. KOTT: I'm going to object to the form. Characterizing consent, this is a discussion.

BY MS. MOORE:

Q. Consent discussion, is that fair to say? Is this a consent discussion, sir?

A. Yes. Well, when you look at these, you're comparing two different things here. Because what we have got here as reference that you had -- that you read with Charlene Taylor, it was for the stress incontinence and then you're comparing that here to the discussion I had that's documented here as it relates to the pelvic enterocele.

Q. Would you look at the following paragraph, sir?

A. Okay.

Q. And does that --

A. I don't see that it says anything about the bladder issue that you described.

Q. If you will pass it back to me, please.

MS. KOTT: Let him keep that one.

MR. KOTT: Keep that one.

BY MS. MOORE:

Q. The paragraph that I'm referencing is the

second paragraph under vaginal enterocele.

A. I see one paragraph, so the first one?

MS. CAPODICE: It's the paragraph entitled vaginal --

THE WITNESS: Right. And you read the failure urinary retention from the stress incontinence. But I'm not seeing that listed below in the Prolift counseling in Taylor.

BY MS. MOORE:

Q. Failure urinary -- if you go up to -- did you do a TVT on Mrs. Morrow? Yes, you did.

A. I did.

Q. And my question to you is, in the Taylor case when you did the TVT, you warned her of the potential of a failure of urinary retention, but you do not appear to be warning her of that in this particular visit?

A. Who? Are we jumping back and forth here?

Q. We are.

A. So you're asking me did I reference the potential for TVT in Mrs. Morrow?

Q. Not the potential for TVT. There's a specific risk involved in the failure of urinary retention that you warned Ms. Taylor about, and when

you were discussing the potential risks involved with the TVT surgery. And I'm asking you why you did not warn Mrs. Morrow about that same risk in the TVT surgery?

A. Because the preoperative evaluation wasn't done.

Q. Okay. So you did not do a pre-op evaluation?

A. No, we were still in process.

Q. Okay. We'll see that as we move on you think?

A. Yes.

Q. Okay. And then look at your pre-op -- Morrow, look at pre-op exam now. This is going to be on page -- the second to the last page -- I'm going to mark it to kind of streamline this. This is going to be Exhibit No. 59, take a look at the second to the last page. And so your Counsel has it, it's an office visit of July 3rd, 2008. I believe it is what you have, but we have a little different format.

A. Okay.

(Exhibit No. 59 marked.)

BY MS. MOORE:

Q. If you look to the second to the last page and you go down under pelvic enterocele --

MS. CAPODICE: Bates page 49 for the record.

THE WITNESS: Okay. This is July -- but this is of the July 3rd visit, right?

BY MS. MOORE:

Q. If you turn to the first page, sir.

MS. CAPODICE: It's on the last page.

BY MS. MOORE:

Q. It's under Tina Morrow visit date Thursday, July 3rd. Right here.

A. Okay. Yeah. I'm just making sure I have the records here. I'm just trying to make sure I'm on the --

Q. It didn't make sense to us either.

A. I don't know why it all printed out this many pages and this is just --

MR. KOTT: It's a different format.

BY MS. MOORE:

Q. So if you turn to the second to the last page of what we have now marked as Morrow -- I'm sorry -- Morrow Exhibit No. 59, under pelvic enterocele. Preoperative plan, risks discussed.

Take a look down there and tell me if you see the risk of failure urinary retention.

A. You're asking do I see those words?

Q. Yes, sir.

A. No, I don't see those words.

Q. Okay. And my question is, a couple months later, your consent changed and why is that?

A. As we -- this is a verbal discussion consent and then there's a written. So what I write down is verbally what we specifically discussed. And it's unique to that individual. So, for example, Ms. Taylor did not -- she already had a hysterectomy, so there's no reason to discuss with her an incidental oophorectomy as a potential risk versus here that might be indicated. So it needs to be --

Q. Tailored?

A. -- customed and tailored to each individual client.

Q. And did you get Ethicon's feedback on that?

A. No.

Q. Why not?

A. This was a discussion, he wasn't in the

room with me when I was talking to my patient. That's a HIPAA violation.

Q. But you're having risk discussions and did you want to discuss with the Ethicon rep what Ethicon thought about these risks associated with the mesh surgeries?

A. As I think we have discussed this before, when I formulated the written consents and it was based on the available literature easily findable at that time, and this company bringing a new product to market, I wanted to make sure that what I was claiming the literature supported about the safety and efficacy of this product, that Ethicon agreed with, because they were bringing this new procedure to market.

Q. And it had been on the market for how many years in 2008?

A. The Prolift first came on the market in 2005.

Q. Two years?

A. Roughly. I think it was mid 2005 it came out. So two and a half years.

Q. So it was important to discuss with Ethicon some risks, but not all of them?

MR. KOTT: Object to the form.

THE WITNESS: No. If you're developing a consent risk on a new procedure, okay, the power of evidence available at the -- on the procedure itself is by the creator of the product, the creator of the technique. So the power of evidence lies there. And so that obviously has to be a resource -- a resource to utilize in that.

BY MS. MOORE:

Q. And the power of evidence from the manufacturer is more important than the power of evidence from the person who actually does the surgery, and has the experience?

A. Can we look at power? What you're doing is you're looking at volume of studies. You're looking at patients. I'm one surgeon versus multitudes of surgeons.

Q. Right. You're one surgeon doing the surgery not the other surgeons?

A. That's correct. That's correct. But when you look at the power of it, you have to bring it all in.

Q. And what's more important in the end, your

experience, right, sir?

MR. KOTT: Object to the form.

THE WITNESS: The objective is to not hurt the patient. First, do no harm.

BY MS. MOORE:

Q. First, do no harm. And you believe it was best to put the lower risk in, that would be more beneficial for your patient, despite the fact that you had concerns about that risk?

MR. KOTT: Object to the form.

THE WITNESS: No. Again, I think I showed you that the evidence available at that time readily provided that risk profile.

BY MS. MOORE:

Q. Now, you can't have it both ways. You're saying on one hand, this is what the evidence said, and this is what I'm hearing from Ethicon. Which one is it?

MR. KOTT: Object to the form.

BY MS. MOORE:

Q. I'll withdraw the question.

A. Okay.

Q. But you can't have it both ways, can you?

MR. KOTT: Object to the form.

MS. MOORE: It sounded so good. Strike that.

MR. KOTT: Object to the form twice. You still want to try to answer that? "You can't have if both ways," I think it's a question that Counsel has proposed -- proposed to the witness.

BY MS. MOORE:

Q. It seems -- it seems you're in a little bit of a quandary, aren't you, Doctor?

MR. KOTT: Object to the form.

THE WITNESS: I don't think so.

BY MS. MOORE:

Q. Let's move on. So what is a -- well, what is an incident -- what is an incidental oophorectomy? Is that vaginal -- where you're closing the vagina?

A. No, incidental oophorectomy is referencing the ovaries.

Q. Okay. All right. And then the failure of urinary retention, did -- you did not discuss with Mrs. Morrow?

A. Now, you're referencing what was discussed with Ms. Taylor?

Q. Yes. And I'm questioning why you did not discuss that with Mrs. Morrow.

A. Again, this is a documentation of a verbal discussion.

Q. Right.

A. So I was only going to document what we verbally discussed in broad, and so I don't know why.

Q. I just didn't know if the rep told you it was not important to discuss --

A. Again, the rep was not in with me with the patient.

Q. You were relying on what the rep had told you, and so I didn't know if they passed on anything about failure of urinary retention?

MR. KOTT: Object to the form.

THE WITNESS: No.

BY MS. MOORE:

Q. The only aspect of information that you relied on from the Ethicon rep was about erosion rates?

MR. KOTT: Object to form.

THE WITNESS: No, that's what you were asking the questions primarily was about the

erosion rates.

BY MS. MOORE:

Q. What other things in your consent -- and we'll turn to that now -- did you rely on from Ethicon?

A. In broad, it's the effectiveness and all the complications and side effects associated with it.

Q. In your consent -- let's see. That's TVT-O. I'm going to hand you the consent that was used with Mrs. Morrow. And --

MS. MOORE: We have got one for you in a second.

MR. KOTT: Kim, can you be more concise now? We are using consent in two terms. One to reference the recording in the exam, and then the other one I think you now mean the form that was signed by the client.

MS. MOORE: Give me one second, Counsel, and I'll --

MR. KOTT: You'll straighten that out. Thank you.

BY MS. MOORE:

Q. It looks like you now have -- may I see the notes that you're making on your report, please?
A. Sure.
Q. Different patients, different -- the record reflects -- I'm looking at your notes. Different patients, different risks. "Taylor's previous hysterectomy, no need for incidental oophorectomy. Evolve." What does evolve mean?
A. It means that with new knowledge, things will change.
Q. Meaning the consent and warning?
A. Exactly. And the safety and efficacy of the device.
Q. And knowledge about that?
A. Well, that comes with time.
(Exhibit No. 60 marked.)
BY MS. MOORE:
Q. Okay. So let me hand you the consent we'll mark as Exhibit No. 60: These are the Tina Morrow written consents.
MS. KOTT: All three of them?
MS. MOORE: Yes. And they are dated July 3rd, 2008. And then there's a mesh consent dated August 12th, '08. And I'll mark

that as Exhibit No. 61. And then finally another Tina Morrow consent.

MR. KOTT: The first one looks like a general consent, and then there seems to be -- they are kind of -- it seems to be --

(Exhibit No. 61 marked.)

BY MS. MOORE:

Q. The first one seems to be what we've seen as the mesh consent. And it's a three-page document. It says number one under one.

A. Looks like you duplicated the first two pages.

MR. KOTT: Yeah, something is screwy.

BY MS. MOORE:

Q. Placement of polypropylene mesh is the first one.

A. Yeah, but what I'm saying, it looks like the first page is a duplicate.

MS. MOORE: There may be. There's two different Bates numbers.

MR. KOTT: I see it now.

MS. MOORE: In an abundance of caution we did not want to pull what we wanted -- so the first one --

MR. KOTT: May I show him? It's a duplicate first page.

MS. MOORE: I don't know for sure why, that's how it came to us. It may or may not matter. And then the second one is TVT/TVT-O. TVT-S circled.

MR. KOTT: Correct.

MS. MOORE: All right. And that's another two-page document.

MS. KOTT: A third --

MR. KOTT: Is there a third? Let's go off the record a minute. You want to go off the record, Kim, and try to straighten it out?

MS. MOORE: What's No. 61? I'm sorry, I might have handed you --

VIDEOGRAPHER: Okay. We are going off the record. The time is 10:10.

(Off the record.)

VIDEOGRAPHER: Time is 10:14.

MR. KOTT: Make copies of them after you finish them.

MS. MOORE: Absolutely. This will now be Exhibit No. 61, which is going to be, I believe, the complete set of consents that Dr.

Goodyear had Mrs. Morrow sign.

MR. KOTT: Exactly. Perfect.

MS. MOORE: And so having said that if you --

MR. KOTT: May I give it to him?

MS. MOORE: Absolutely.

BY MS. MOORE:

Q. Take a look at that. And, Doctor, we have looked at, you know, consents for your other patients, and seen, I believe, in many instances, if not all, where you have gone through the consent for the TVT, for the mesh, and for the Prolift; is that fair to say?

A. TVT, the mesh, and the Prolift, yes.

Q. It would be your custom to take the time to discuss, as you have in the office, the risks that you believe to be important and then take the patient through the actual consent, provide them with an opportunity to ask questions, and then have them sign it and have it witnessed?

A. Correct.

Q. And if you look, for example, under the mesh risk, you discussed with the patient, obviously, the purpose of the surgery and the

alternatives of the surgery and the fact that there are no guarantees, correct?

A. Correct.

Q. And I think we've read this into the record a couple of occasions, but it was important for you to document, to discuss, the items that are listed on -- for example, if you turn to the following risks known to be associated with this treatment, have been explained to me. Next page, beginning with brain damage?

A. Yes.

Q. And it goes all the way down and it talks about some of the risks here. And it says, "infection and erosion." Now, in this particular signed one in July of 2008, is there a reason why you took the 3 to 5 percent out?

MR. KOTT: Object to the form.

THE WITNESS: I don't know why that's not there.

BY MS. MOORE:

Q. I didn't know if that was a result of information you were getting at the time in the 2008 period?

A. Again, I think it's --

MR. KOTT: Hand those to me, please.

THE WITNESS: If I remember correctly, one did not have 3 to 5 percent, the written; and it was the verbal where that was quoted.

BY MS. MOORE:

Q. Right. So this one is a signed one, though?

A. Yeah, but what I'm saying, I don't think that was ever there. I think it was in the verbal that was there. The percentage quote.

Q. And I can show you, it's also in the written consents and others.

A. Okay. I don't know why it wasn't there.

Q. That's my question. I did not know if the -- did the Ethicon sales rep tell you to delete the reference?

A. Well, this predated, I believe, Ms. Taylor, so --

Q. Wait. No, I'm talking about -- this is in '08?

A. Right.

Q. So when did you have the discussion with the Ethicon --

A. Again, the conference was in '08. You

wanted me to try to nail it down.

Q. The conference is in '08?

A. I think what you're trying to say, if there was a change in percentage. You're trying to say that the percentage here -- Mrs. Morrow, her surgery occurred before Ms. Taylor?

Q. Right.

A. Okay. So I quoted a three point -- 3 to 5 percent for Ms. Taylor. Who occurred -- the surgery was in August. So that is a surgery after this one. So the 3 to 5 percent would still apply that I would have quoted here. So I did not -- hadn't changed the 3 to 5 percent.

Q. Okay. That's what I want to make sure. And there was no -- I just want to make sure when there's a different patient or different time period, if there was anything going on with the sales rep that you recall that altered what you were doing or what you were saying to the patient?

A. No.

Q. So this one is silent on potential risk, but you did discuss erosion?

MR. KOTT: Object to the form. Silent on potential risk. Vague.

MS. MOORE: Silent on -- withdrawn on my question.

BY MS. MOORE:

Q. Your consent here with Mrs. Morrow is silent with respect to the percentage range for erosion, correct?

A. Correct. That's not listed here.

Q. All right. And you continue throughout this to risk -- a list of the risks of other things that we have talked about, and that would be, for example, failure for improvement or even temporary improvement. It says failure improvement -- lack of improvement?

A. Can you reference where you are?

Q. Yes. The last one down says --

A. Is that number five?

Q. No, I'm kind of looking at -- the section here I'm pointing to, it says, "The following risks known to be associated with this treatment have been explained to me." This is under placement of mesh. Do you see that, sir?

A. Yes. This is the second one, correct.

Q. Yes, sir. And I just wanted to make sure I understood, you talked about "there is a

possibility of lack of improvement, being the patient will not get better"?

A. Correct.

Q. "There is a possibility of a temporary improvement, you might get better for some time and then return to baseline or get worse"?

A. Correct.

Q. And then you could have a "failure of urine problems, control or prolapse symptoms again"?

A. Correct.

Q. Discomfort with sexual intercourse?

A. Correct.

Q. So all of these risks that are in here were known to you before you did surgery on Mrs. Morrow, Mrs. Shively, and Ms. Taylor, correct?

A. Correct. The issue, though, is the underrepresentation of the degree of the risk.

Q. Okay. Now, that's a good point. Because in your -- if you go right underneath what I just read, it says, "I have been informed of the probability of occurrence of each of the above risks as the result of or in connection with the surgical or medical procedure contemplated herein.

What probability of occurrence did you

provide Mrs. Morrow for each of the risks in connection with the surgical or medical procedures listed above?

A. I don't know what probability I quoted for them.

Q. Okay. Well, it's in your consent.

A. "I have been informed, Mrs. Tina Morrow, there's a probability of surgical repair. Mrs. Tina Morrow, there is a probability that this mesh will create chronic inflammatory response and result in erosion risk. Mrs. Tina Morrow, there's a possibility." So there were certain aspects where the probability was general probability.

Q. So you're saying --

A. Because this was a new procedure.

Q. -- probability of occurrence not possibility?

A. Probability. Possibility. Possibility (sic).

Q. Let's use the words that you chose for your consent, or was this language that came from Ethicon?

A. This language was not from Ethicon.

Q. Okay. You want your patients to affirm

that they have been informed by you of the probability of occurrence of each of the risks -- above risks as the result of or in connection with the surgical, medical procedures contemplated herein. And I'm asking you what was the probability of occurrence for each of the above risks that you shared with Mrs. Morrow on or before July 3rd, 2008?

A. I don't recall what I quoted her. I'm sorry, I thought I just opened her water.

Q. Go ahead and attach that, please. Let's turn then to -- we'll attach those consents. And then -- it was -- were you aware that Mrs. Morrow testified that on July 3rd of 2008 -- strike that. I apologize.

On October 29th, 2015, that she wasn't having any symptoms at the time you told her and recommended that she have surgery?

MR. KOTT: Object to the form.

THE WITNESS: Actually, I think I pointed out that she was having symptoms of bloating, stress urinary incontinence, and urgency associated with incontinence.

BY MS. MOORE:

Q. If she were to testify that -- the question, "Was that because you weren't having" -- strike that.

"What do you recall about the visit on July 3rd, 2008, with Dr. Goodyear?"

"That he said I had a prolapsed wall and my colon had fell, too. But I also remember that I was shocked by that, and that I was going to have to have surgery."

And question, "Why were you shocked?"

"I did not know. I did not realize that it was -- that it needed to be."

Question, "Was that because you weren't having any symptoms that you recall?"

Answer, "Nothing I can remember. I guess, maybe there was pressure. But I just -- I don't know that it was bad. I had trouble using the bathroom, a bowel movement."

Do you recall any discussions with Mrs. Morrow about not really having symptoms that would necessitate surgery?

MR. KOTT: Object to the form of the question. Misstates the testimony.

MS. MOORE: We are going to attach that

testimony to the deposition as Exhibit No. 62.

MR. KOTT: I object to it being attached unless the whole deposition is attached.

MS. MOORE: You want to attach the whole deposition? We'll attach that section, if he wants to pull something else out.

BY MS. MOORE:

Q. And then let's go to the next step --

MR. KOTT: She said she's not going to. If I wanted to do it --

MS. MOORE: You know what, Counsel, I'll be happy to print the whole thing. It's not a big deal.

(Exhibit No. 62 marked.)

BY MS. MOORE:

Q. July 11th, 2008, I have that you're doing a POP exam. You told us about that yesterday, correct?

A. Correct.

Q. And your results from that POP exam, you pretty much had a sense already according to your testimony a few minutes ago, right?

A. The results of the POP-Q are in here in her medical records.

Q. Right. But you had a pretty good idea before you did the POP-Q of where she would be as far as --

A. As I discussed earlier, usually, stage one, stage two, it's pretty obvious, and the POP-Q basically gives you confirmation.

Q. And let's go to the actual surgery, August 12th, 2008. And --

A. The operative report, is that where we are going?

Q. Yes, sir. And just basically --

A. And what was the date of that?

Q. August 12th, 2008.

A. Okay.

Q. And your findings on that date were very large enterocele. Mid-high, low rectocele. Paravaginal defects with proximal cystocele. Normal bladder urethral mucosa with negative cough test, correct?

A. Yeah. When I look at the preoperative diagnosis, I see stage two enterocele. Stage two vault prolapse. Stage two cystocele with paravaginal defects, stress urinary incontinence.

Q. Right. And I was going to the findings

after you did surgery, that's what I was reading from. I apologize, I wasn't clear.

A. Okay.

Q. And it appears that the surgery was without complication?

A. My recollection is correct and as stated.

Q. And it's also referenced in your report?

A. Sure.

Q. August 18th -- I'm just going to move through these, so you might just want to follow. And, of course, anytime you want to look through something --

A. The way these are laid out, I'm going back and forth. So August --

Q. August 8th, and then we'll go to August 25th, kind of in chronological order. If you want to take a minute and go off record to fix that, would that help you?

A. August 25th.

Q. Okay. It appears she --

A. Hold on a second. I jump from July 25th to August 18th.

Q. Thank you. You're with me.

A. Great.

Q. All right. Says, "post-op visit." And she is feeling worse. She passed a large clot after having trouble with her bowel movement. And she had bled significantly. And she had a lot of strain that weekend. So what -- just help me understand what's going on with this particular patient. This is post surgery and she's having difficulty with her bowel movements. Is that as a result of anything with the surgery or is that her constipation or a combination of factors?

A. It's a combination of factors.

Q. All right. And go to the next visit, that's just about a week later. She's still hurting --

A. Just for verification it's August 25th.

Q. Thank you. About a week later.

A. Yeah.

MR. KOTT: Excuse me, does anyone have their luggage out by the elevator?

MS. CAPODICE: It's probably mine.

MR. KOTT: I'll get it, I'll get it, if you will just hold off a minute.

MS. MOORE: If anybody wants my dirty underwear, and you can put that on the record.

MR. KOTT: Don't do that. Turn off the thing. I'll get it, okay.

VIDEOGRAPHER: We are off.

(Off the record.)

VIDEOGRAPHER: All right. We are back on the record. The time is 10:32 a.m.

BY MS. MOORE:

Q. Doctor -- strike that.

Doctor, we are going through Mrs. Morrow's visits with you. And I believe we were on August 25th, '08. She returns for a follow-up visit. She's still hurting. That means she's still hurting in what particular area, any reference, post-op?

A. Well, we did the surgery in the pelvis, so I would assume to be pelvis anywhere.

Q. So that would be kind of normal, especially post-op?

A. Immediately post-op.

Q. All right. She's negative for dyspareunia. So she's not having --

A. She wouldn't be sexually active at the time.

Q. At that time. Dyspareunia, nocturia,

polyuria, vaginal discharge or itching.

Let's go to the next visit, September 8th. Looks like she doesn't have any complaints; is that true?

A. Yes. It says well -- "no complaints. Still with some Valsalva to move bowels. Taking stool softeners, no bulge, no odor, pain much improved."

Q. And why was she still requiring -- and for the ladies and gentlemen of the jury, what is Valsalva to move bowels? Is it what we talked about before?

A. Valsalva is simply bearing down, abdominal pressure, to evacuate.

Q. Why was she requiring, or needed, Valsalva to move her bowels?

A. Couple things. Number one, she's still in the immediate post-op period.

Q. And, again, negative for any kind of abnormal vaginal bleeding or vaginal discharge. And then a follow-up, again, I have in September 28th, she's -- September 28th, 2008. And she, at this point, complains of "still with abdominal soreness and some small bleeding"; is that right?

A. That's what's recorded there, yes.

Q. All right. And if you look under genitourinary, it looks like you're examining her genital area, you see that the trocar sites were well healed. "Vagina suture lines intact without exposure. Stress test negative." And then you "cut the proline suture anteriorly. Small spread of graft anteriorly. Cut and removed, none palpable." What are you doing, what does that mean?

A. Well, when I did the exam there, it looked like there was what appeared to be a small suture, but it's hard at that stage of the game sometimes to tell between the suture and maybe a small piece of exposed mesh.

Q. Okay. So in your expert report, if you look at your reference at six weeks -- are you with me?

A. Yeah.

Q. It says "six weeks post-op, 9/22/08. A small piece of mesh, or less likely suture, was noted anteriorly on exam." Why are you saying less likely suture when at the time you actually did the exam, you put PROLENE suture?

A. Because when -- the typical suture we

would use would be a fairly rapidly absorbing microl. And so -- though it can stay longer than the company currently recommends -- says that it stays, it can kind of give the appearance, if it's cut really short, of a PROLENE. So without actually opening it up and saying what is this, it's really hard to assess that because you don't want to do a lot of digging in and around that area.

Q. Fair enough. And so at this point you just weren't really sure one way or the other?

A. Correct.

Q. Okay. Let's move forward to October 6th in 2008. She's having some bleeding. "Still having bleeding, especially after bowel movements. Her pain for the most part is resolved and she's feeling better." You note on exam, "good pelvic support. Small exposure proximal anteriorly, small exposure at the posterior fourchette," correct?

A. That is correct.

Q. And you're doing a -- you ask her to do a consent for reclosure of incision?

A. Following that exam, correct.

Q. All right. Now, looking at your expert report on your reference to October 6th, 2008 --

A. Yes.

Q. -- it says -- you reference increased blood discharge. And I don't see the word increased in your notes on that day.

A. That's October 5th?

Q. October 6th.

A. Oh, I'm sorry, 6th, yes.

Q. And under the history and physical, has a brown discharge all day long with strong odor. Still with blood discharge. I just did not see the word increased in your notes. Did you add that in your report?

A. Yeah. It was a continued vaginal bleeding.

Q. Not necessarily increased, but continued?

MR. KOTT: Object to the form.

THE WITNESS: Yeah.

BY MS. MOORE:

Q. Is that correct?

A. Correct.

Q. Okay. And we go to October 4th when you're doing the procedure. You're removing vaginal exposure of mesh and reclosure of the vaginal mucosa. At this point you're seeing --

A. The October 4th operative?

MR. KOTT: 14th, I believe.

MS. MOORE: 14th.

MR. KOTT: I think it's the 14th.

MS. MOORE: I believe you're right. I hope I clarified that.

BY MS. MOORE:

Q. Let the record reflect I believe it's October 14th, Doctor.

A. Thank you. I'm not seeing that operative report.

Q. Okay. No problem.

MS. KOTT: It's in the hospital records.

MS. MOORE: We are going to mark that as Exhibit No. 63.

(Exhibit No. 63 marked.)

BY MS. MOORE:

Q. Take a moment and look at that. If you look at the record here: Removal of vaginal exposure of mesh. The closure of vaginal mucosa. And no complications, correct?

A. That's how it reads, correct.

Q. And this was -- let's see. And it was "removed via curved Mayo's very easily." What does

the removed via curved Mayo's very easily mean?

A. You're asking me to go back and try to review what I was thinking when I dictated that. But it means that I was able to cut the exposed mesh -- it cut very easily, there was not -- that's typically what it means.

Q. And once you did that, there was no palpable visible mesh exposed at that point?

A. Correct. That's how it reads.

Q. And you have no reference in here to any type of fraying or roping or degradation with the mesh that you trimmed?

A. Not as it relates to, you know, this particular aspect of Mrs. Tina Morrow, no.

Q. Well, any aspect of Mrs. Morrow, there's no reference to anything in your report?

A. Correct.

Q. And, in fact, in all the reports that we've seen so far, you have not documented where you've seen fraying, roping, or degradation in any of the mesh that you have excised, correct?

A. Correct. But it wasn't in a lot of these women and a lot of information available at that time in terms of the fraying, etcetera.

Q. But, Doctor, you have never noted anything about any particular aspect of mesh once you've excised it?

MR. KOTT: I'm sorry --

MS. MOORE: Correct?

MR. KOTT: I'm sorry. Object to the form. I may not object. You asked if he had noted it in his record?

MS. MOORE: Yes.

MR. KOTT: Sorry, no objection.

THE WITNESS: Not noted in the record.

BY MS. MOORE:

Q. Or any of your records?

A. I've got Tina's in front of me, so I can't be completely --

Q. Well, if you had seen something, you would have noted it?

MR. KOTT: Objection to the form.

THE WITNESS: Correct.

BY MS. MOORE:

Q. Let's continue. You also saw a small exposure posteriorly at the posterior fourchette that you also removed, correct?

A. Correct.

Q. Did you send the specimen to pathology?
A. Pathology. No, I did not.
Q. And why not?
A. Again, you're asking me to go back to that point in time, I don't know.
Q. It just wasn't something that you deemed to be necessary at that point?
A. Well, they were small. And so --
Q. Small incisions, not significant?
A. Small --
MR. KOTT: Object to the form.
THE WITNESS: Small, typically being very little to send off.
BY MS. MOORE:
Q. Thank you. And then post-op -- I think we got this. Let's see. Post-op you did not palpate or see any mesh?
A. What day of the visit would that be?
Q. Well, let's just look at 11/6/2008.
A. I'm there. Okay.
Q. She's doing great here, right? But "still with straining with her bowels"?
MR. KOTT: Object to the form.
THE WITNESS: That's how it reads,

correct.

BY MS. MOORE:

Q. So she's doing better. And why is she "still straining with her bowels"?

A. There could be, again, a variety of reasons, because this is now a -- where we have repeated a surgery, so still extended healing process possibly going on.

Q. And there are negative -- "suture lines are intact without evidence of exposure," correct?

A. That's how it reads, correct.

Q. Let's go to November 24th. Another follow up. Negative for lesions, hematuria, menstrual problems, polyuria, abnormal vaginal bleeding, and discharge. So she's not having any of those types of problems, correct?

A. That is correct.

Q. And let's look at your expert report. I believe it's on the first page at the bottom of the page, beginning with postoperatively.

A. Okay. Yeah. The very first word, yeah.

Q. And you say postoperatively the pain and bleeding persisted.

A. This is under clinical summary. What

paragraph?

Q. It's on --

A. I've got it, very bottom of the page.

Q. So you say postoperatively the pain and bleeding persisted. But she wasn't having any pain and she wasn't having bleeding, at least of the last two couple of visits, right?

A. Yes. At least per the last couple of visits. Let's go back to the last one, that page. That is correct.

Q. Okay. So is that an error?

A. No, I wouldn't say it was an error, it's just at this point in the chart, she wasn't having --

Q. Well, why did you not --

MR. KOTT: Whoa, whoa. Please let him finish his answer.

BY MS. MOORE:

Q. Please finish.

A. At this point in her chart, at those particular times, visits, I did not, you know, see any. But when you look at the extent of her follow up, she continued to have it.

Q. All right. Why did you not reference that

she's doing great and no pain and bleeding noted in your expert report during the October, November 2008 time period?

A. Just like the same way where I did not put that she was still requiring Valsalva and splinting, I don't know why I didn't include those.

Q. So you just put problems with pain and bleeding persisted?

A. Correct.

Q. Is the persisted correct, because it's not persisting?

MR. KOTT: Object to the form.

THE WITNESS: Well, persistent means something that occurs, that's just typically what it means.

BY MS. MOORE:

Q. Is persistent ongoing?

A. Not necessarily.

Q. What does persistent mean to you?

A. Persistent to me means that it's something that has continued that existed before. That doesn't imply that it's a continuous process.

Q. Okay. What you mean here is postoperatively the pain and the bleeding --

A. Because a lot of times what will happen in these cases is you have a very small amount of vaginal bleeding and it will stay in the vaginal vault and they won't notice that for potentially hours to days and then they move and it will come out.

Q. Move to strike anything about the vaginal vault.

But -- so if we were to make this accurate postoperative, the pain and bleeding occurred sometimes?

MR. KOTT: Object to the form.

THE WITNESS: I'm sorry, can you re-ask that question?

BY MS. MOORE:

Q. Let's keep going to see what you mean by persistent. Okay?

A. Okay.

Q. Because we are now in November -- January of 2009. And let's look at your notes. And --

A. January -- what's the date?

Q. 30th, 2009.

A. I'm there.

Q. And from the history -- she comes in with

some occasional spotting. And history and physical, her husband noticed a rough area during intercourse. No pain per Tina.

A. That's with reference to intercourse.

Q. So she's not having pain. Let's see if you see evidence --

MR. KOTT: Object to the form.

BY MS. MOORE:

Q. Look at your note there and see if you see any indication of persistent pain on that visit?

A. Well, if you look in the context of that, she's referencing intercourse.

Q. Any pain. I'm not limiting it to just -- so she's not having pain with intercourse, she's not. Her husband, obviously, has noticed what has been described here. My question to you is, though, with respect to your comment in your report that Mrs. Morrow had persistent pain. Once again, we see a record where there is no evidence of Mrs. Morrow having pain?

MR. KOTT: Object to the form.

THE WITNESS: There's pain with intercourse. There can be pain otherwise.

BY MS. MOORE:

Q. Where is there evidence of any pain?

A. Well, this right here is referencing intercourse. That's all I'm saying. What is written here is with reference to intercourse. So in terms of what she told me was, I'm here because I'm -- my husband is noticing there's something there that's painful.

Q. All right.

A. Now, that's not painful to her, that is the act of intercourse. But there's no confirmation that -- is there pain outside of that, because that's what she was --

Q. Your records do not indicate that she was having any type of pain on the visit of January 30th, 2009, correct?

A. That would be correct.

Q. So there's no evidence that pain is persisting on this particular visit, correct?

A. On this particular visit, she is not claiming that there is pain at that moment.

Q. Would you rely on her to tell you if she was having pain?

A. Well, of course, I would. Who else would I rely on?

Q. Well, we had seen in the last three visits no pain, but yet you're saying pain is persisting?

MR. KOTT: Object to the form.

THE WITNESS: Again, in the total scope, pain persists. As I mentioned with the vaginal bleeding, there can be an interval where there's no bleeding, because it collects. These things can come and go. We are not talking about continuous.

BY MS. MOORE:

Q. Okay. Let's keep going then. Let's see. There's no evidence of --

A. Where are we now?

Q. I'm still on that visit -- that visit being January 30th and -- "atrophic mucosa moderate" --

A. January 30th?

Q. Yes, sir. And there was "good pelvic support," correct?

MS. KOTT: What date are we on?

MS. MOORE: January 30th, 2009.

THE WITNESS: Okay. Sorry. Would you please re --

BY MS. MOORE:

Q. "Good pelvic support?"
A. This is on exam?
Q. Yes.
A. Okay.
Q. "Good pelvic support. Atrophic mucosa?"
A. Correct.
Q. "Moderate?"
A. Correct.
Q. What, again, is the "atrophic mucosa"?
A. Again, that's the thinning of the vaginal mucosa.
Q. And what can that -- what complications could one see as a result of atrophic mucosa?
A. You could have a thinning of the vaginal mucosa, so you can have irritation, dryness, you have decreased blood flow to that area.
Q. Occasional spotting?
A. It can, yes.
Q. The occasional spotting that's referenced on that January 30th, '09, what did you attribute that to?
A. I did not specifically direct what I attributed it to, so I can't comment on it.
Q. Let's go to July 8th, 2009.

A. July 8th, 2009?
Q. Yes, sir.
A. January 30th. I go to March 19th.
Q. I have July 8th. It's an office visit.
A. Okay. July 9th, the next page.
Q. All right.
A. Out of order.
Q. She's saying, "no pain with intercourse. Some bleeding recently, though husband says it is rough at times." So there's no -- take a moment, please, look at the entire report. Is there any evidence that Mrs. Morrow complained of any type of pain with intercourse or otherwise to you on that particular visit?
MR. KOTT: That's a fair question.
THE WITNESS: I don't see that documented either.
BY MS. MOORE:
Q. So the pain, again, is not persistent, we have not seen pain at all?
MR. KOTT: Object to the form.
THE WITNESS: In here it's in reference to intercourse.
BY MS. MOORE:

Q. All right. My question, though, was -- and you told us earlier, it would be your custom and your habit when taking a history to write down anything significant, any complaints the patient has, correct?

A. That is correct.

Q. And is there a complaint of pain referenced on the July 8th, 2009 visit by Mrs. Morrow?

A. There is not.

Q. So there is, again, no evidence of persistent pain that we have seen since immediately post-op to at least through July 2009, correct?

MR. KOTT: Object to the form.

THE WITNESS: That we discussed or that I asked, correct.

BY MS. MOORE:

Q. Well --

A. She wasn't aware that she had a stage two prolapse.

Q. You're saying she may have pain but not know it?

A. No. The reference when she came in was with regards to the intercourse and the pain that

her husband was encountering.

Q. But if she had any pain and documented -- and told you that, you would have recorded it?

A. That is correct.

Q. Okay. So there's evidence in your records of persistent pain, correct?

A. The visit was about the painful intercourse.

Q. Why are you fighting me on this?

MR. KOTT: Objection. Objection. Commentary. Argumentative. Interruptive. Rude.

BY MS. MOORE:

Q. All right. Is there any evidence of pain in any of the records that we have discussed post-op until July 8th, 2009?

MR. KOTT: Kim, the problem is there are references to pain, you want to know if she -- okay, then you're going to get the same answer.

THE WITNESS: In my records here with the visits related to what you're referencing, it's about intercourse, and there's no reference to pain that she's saying there, it's all reference to her husband. But outside of that

there are episodes where pain is attributed beyond.

BY MS. MOORE:

Q. Where?

A. Other visits.

Q. Okay --

A. Beyond mine.

Q. Okay. I'm just talking about during this time period.

A. Well, these particular two here, no.

Q. No, it's more than two.

A. Well, I mean, the ones that you're referencing.

Q. There's no evidence of pain?

A. Beyond the intercourse, as I've said several times here, there is no other documentation here.

Q. So there is no evidence of pain recorded of any type in any of the visits we have discussed postsurgery?

A. An individual -- a woman can have pelvic pain with certain positions, standing, walking --

Q. But she did not report that to you?

A. -- and then say -- and then say, well,

does it hurt when you have intercourse? No, it doesn't hurt. There are very different processes. Because if you're talking about a nerve entrapment potentially with a mesh, as it relates to the healing process, that can create a radiation or radiculopathy type of pain. So that can be a chronic ongoing pain that is different. These visits are specifically about the dyspareunia. So there may not have been any questioning beyond that point. These were specifics about what her husband was encountering as it relates to intercourse.

Q. Oh, there were limited visits, you did not ask her how --

A. Her complaints were with regards to that.

Q. Right. No complaints on anything else, right?

A. Not that she said.

Q. And you wouldn't have limited her and said, I don't want to hear about anything but your problems with your husband's pain?

MR. KOTT: Objection.

THE WITNESS: Now you're leading to say I would say that. I would never say --

BY MS. MOORE:

Q. I'm not asking you --

A. I would never say something like that. That patient in my office is the most important thing to me. And that's why it's so important what Ethicon did here, and they are representing the risks of this procedure.

Q. And that's what's really messed up everything, right, that's the whole reason?

A. Yeah, because there were a lot of women that were hurt based on knowledge that we did not know and was not given to us by your company.

Q. And we are going to talk about that, but right now the woman we are discussing is Mrs. Morrow. And you've said in your report, and you have signed that report, that she experienced postoperatively the pain and bleeding persistent. Now, we are seeing here a complaint of bleeding, but we have not yet in your records seen any indication of Mrs. Morrow having pain, correct?

MR. KOTT: Object to the form of the question.

THE WITNESS: I think I've already answered that.

BY MS. MOORE:

Q. I'm going to ask you to answer it again.
A. I seem to answer a lot of questions multiple times.
Q. Well, I'm sorry, sir, that's part of the process when you are trying to evade the question.
A. I'm not trying to evade.
MR. KOTT: Objection. Objection.
MS. MOORE: Then answer the question.
MR. KOTT: Hold on a second. I object to this ongoing commentary. I object to the arguing with the witness. And I know that this is a long orgulous process, but please ask Counsel to stop and gather herself.
THE WITNESS: There is no documentation here when she comes in talking about these visits, I'm here with pain with intercourse, per her husband, that she is commenting on pelvic pain herself.
BY MS. MOORE:
Q. Thank you. All right. Let's go on. It looks like that's the last time you saw her for -- until after she got involved in the litigation and hired her lawyers, correct?
MR. KOTT: Object to the form.

THE WITNESS: I don't know when she got involved in litigation, so I can't tell you that.

BY MS. MOORE:

Q. But just so you -- before we move on. Throughout the time you treated her, you said there's no evidence of pain. Let's look at the --

MR. KOTT: Objection to the comment.

BY MS. MOORE:

Q. -- on the last visit, "no erosion, extrusion seen or palpated," correct?

A. Where are you, again?

Q. Under genitourinary.

MR. KOTT: Which date?

MS. MOORE: Sorry. July 8th, 2009.

THE WITNESS: I read external genitalia: Normal external genitalia, without lesions or urethral abnormalities. Vagina, atrophic mucosa. Moderate, as we discussed. Good pelvic support, no erosion, extrusion seen or palpated, correct.

BY MS. MOORE:

Q. All right. Let's go, then, to turning back into your, I believe, your report.

MR. KOTT: We are about two hours in. What time is it now, sir?

VIDEOGRAPHER: You have about ten minutes before reaching two hours.

MS. MOORE: You want to just knock that out and take a break?

MS. KOTT: Yes.

MS. MOORE: I might be able to get through this IME report.

BY MS. MOORE:

Q. Doctor, let's turn to your IME report. I guess before I do that, let me quickly ask questions about your methodology, you talked about that.

MR. KOTT: Can you -- is it --

VIDEOGRAPHER: We have gone over the two hours, that was my mistake.

MR. KOTT: Okay. Can you put -- perhaps, just order that pizza like we talked about?

VIDEOGRAPHER: Let us know what you want and they will go get it.

MS. MOORE: Why don't we take a break?

VIDEOGRAPHER: We are going off.

(Off the record.)

VIDEOGRAPHER: Okay. We are back on the

record. The time is 11:11 a.m.

BY MS. MOORE:

Q. Doctor, before we took a break, we were talking a little bit about methodology. Let's come to that after we get through your complete report, I think that would be easier. So what I would like to do, then, is turn to the section of your report where you had an opportunity to discuss your most recent visit and examination of Mrs. Morrow. And can you tell us about that, please? Beginning with the history she gave you at the time.

A. Can you --

Q. Your report?

A. From that visit. Let me make sure this is correct. November 19th, 2015. Would you like me to read this?

Q. You know what -- let's try to get through this quickly. She presented -- kind of recap -- bleeding and pain has been persistent and has increased in intensity since the surgery. And we have talked about your records, at least, did not show, and we are not talking about other records, we can talk about that in a little bit, but your records did not show persistent pain since the

surgery prior to the November 19th, 2015 visit, correct?

A. That is correct. These are just her complaints that she is telling me at the visit.

Q. Thank you. And then the bleeding during the time period you saw her, we did note some spotting and occasional bleeding in the last visit, correct?

A. Correct.

Q. Which would have been July 8th, 2009. And with respect to that bleeding, are you able to attribute the bleeding to anything in particular given the fact that she had the atrophic vaginitis?

A. The most likely contributing factor was, in fact, the mesh when she had the mesh erosion. Now, on that last visit, which was July 8th; is that correct?

Q. I believe so.

A. She was on vaginal estrogen, so that should exclude atrophic vaginitis as a possibility because that vaginal estrogen is a part of that process of healing it.

Q. That's a good question. Where do you see that she's on that? I know you just described it

but --

A. It's just a continuation of the prescription there.

Q. It's in your records?

A. Well, it just says "prescription Estrace," she had been on it before. It's a continuance.

Q. So you have given her medication --

A. I put her on it before the first surgery -- after the first surgery.

Q. If the records indicate that she was not taking the Estrace during that time period, what -- could the vaginal atrophy be playing a role in the bleeding?

MR. KOTT: Object to the form.

THE WITNESS: Yes, correct.

BY MS. MOORE:

Q. Let's go then, continuing along, there's discussion of -- bleeding, pain has been persistent and increased in tenderness since the surgery. That's based on what she told you?

A. Correct.

Q. Pain was dull constantly and acts as a sharp pain that can be as high in intensity. She can't exercise and walking is painful in doing her

work around the house. That, again, is all based on what she tells you. And then you go forward and you -- your exam, correct?

A. Yeah. Correct.

Q. "Good support." Under genitourinary. "Good support, tight banding with arms bilaterally interiorly. Erosion noted interiorly proximally but just to the left of midline. Anteriorly pain has persisted along the entire graft, maximal at arms. A hard-like shelf area anteriorly is very tender proximally in the midline. Almost contracture like in the arm. Posterior granulation tissue is noted along the midline." I don't know why I had to do that. Strike that. "A very hard shelf-like ridge is noted posteriorly proximally in the vagina. No erosions were seen, nor palpated posteriorly. Bloody vaginal discharge noted." And then I have induration or subcutaneous nodules. Dot, dot, dot. But those are your findings with respect to the mesh, would that be fair to say, sir?

A. That's correct, that's how it reads.

Q. And then your assessment was prolapse in vaginal vault after the hysterectomy?

A. That's, again, just a CPT code. That's

initially what this was involved with, the mesh.

Q. And then if you look at your notes -- I'm sorry. Your notes don't establish -- your personal notes don't establish that she was having persistent bleeding, vaginal discharge, pelvic and groin pain, or burning in the groin area from the initial placement of the product, correct?

A. Can you rephrase that question or ask it again, because I'm trying to get clarity when you say my notes?

Q. Yeah. Look at your report beginning with -- all right. Thank you. Okay. On page three of your report, under "see my notes for the most recent exam"?

A. Correct.

Q. Records attached as Exhibit No. 3. It begins, "vaginal bleeding, vaginal discharge with odor. Pelvic and groin pain and burning in the groin area were persistent from the initial placement of the mesh product."

Do you see that, sir?

A. I do.

Q. Does -- the intensity of the pain has progressed -- progressively increased since the

placement of the mesh product.

Leaving aside what you may have from other sources, just speaking to your experience, treating the patient, that is not a correct statement --

MR. KOTT: Object to the form.

BY MS. MOORE:

Q. -- is it?

A. Well, that's hard to say, because that's what she told me when she came in.

Q. And I'm asking you about -- so this isn't your opinion, this is just resuscitation of what the patient is telling you?

MR. KOTT: Object to the form.

THE WITNESS: And when you look at -- this is basically -- I'm saying what she told me that's happening in intervals since I last saw her.

BY MS. MOORE:

Q. All right. So let me ask you about the claim of vaginal discharge. And if you would like, we can go back through, because I have them right here, every time in your report where it's negative for vaginal discharge. Negative for vaginal discharge. So my question is -- let's go through

each one of these. Vaginal discharge. Isn't it correct that as you sit here today, based on your treatment of Mrs. Morrow, you do not attribute the vaginal discharge to anything associated with the mesh?

MR. KOTT: Object to the form.

THE WITNESS: Well, she's had some multiple erosions and there's a long interval where I don't see her and she comes in with complaints of that, and then on exam -- so I don't know how I cannot attribute it to it, because that's what she told me.

BY MS. MOORE:

Q. During the time you treated her -- I understand that you have just recently seen her since she's been involved in the litigation?

A. December, correct. November.

Q. But prior to that, every time you asked her about vaginal discharge or checked her, there was no evidence of it?

A. Not that I documented.

Q. Not that you documented, meaning there was no evidence of it?

A. Correct.

Q. So how can you say that it's persistent?
MR. KOTT: Object to the form.
THE WITNESS: Because she's talking about this being present and the visits outside of seeing me.
BY MS. MOORE:
Q. I've already excluded that. I'm talking about your care and treatment of her.
A. My expert opinion, it's taking in toto her entire follow ups, including others and myself.
Q. All right. I'm asking you about your care and treatment, though. They can ask you about that in a few minutes.
A. I understand that.
Q. But based on what you have laid eyes on and dealt with with respect to Mrs. Morrow over the years, not until the very last visit did she tell you that she had had vaginal discharge as a result of the mesh, correct?
A. According to my chart, when I saw her, that would be correct.
Q. Okay. So are you discounting your work with her and your care and treatment of her and only basing your opinions on her treatment -- I mean, her

subjective complaints?

MR. KOTT: Object to the form.

THE WITNESS: No. It's taking it in toto, including her last visit with the interval that occurred before where she comes in and says, look, here is what I'm dealing with now and here's what's transpired between now and when I last saw you.

BY MS. MOORE:

Q. Well, then why wouldn't you give any credence to what you observed and instead of saying, it's persistent, say, was not noted throughout the time I treated her, but she reports that it has now occurred and is now reporting it on this visit? Isn't that more accurate?

MR. KOTT: Object to the form.

THE WITNESS: Taking it in toto, in terms of all of it, persistency is simply it's present. It's not saying the volume, the frequency, or anything. It's just saying it has occurred and it's occurred again and it's related to the same product or possibility. Which at this point is simply the recurrent mesh erosion.

BY MS. MOORE:

Q. So you're completely discounting what took place when you treated her?

MR. KOTT: Object to the form.

BY MS. MOORE:

Q. Okay. What role does that have to do here? Why didn't you comment anywhere --

A. Because this comment here was following this visit on November 19th, so it's basically a summary of that visit that encompasses -- sorry?

MR. KOTT: No, no. Please let him answer, please.

THE WITNESS: It's encompassing the extended time frame from which I last saw her.

BY MS. MOORE:

Q. The way I read, and maybe it's me, "vaginal bleeding, vaginal discharge with odor, pelvic and groin pain, burning in the groin were persistent from the initial placement of the mesh product." And there was a time period after the initial placement of the mesh product where she did not have any complaints of any of those symptoms. And I can read them out for you. "August 25th, 2008, negative for vaginal discharge. Negative for

pain." I mean, do we want to go through all of this or can you recall sitting here --

A. I recall sitting here right now.

Q. Okay. I'm just trying to understand, and maybe you can't explain it, and that's -- but why are you discounting what you did and what she told you during that time period and accepting what other doctors are saying and what she's telling you now that she's involved in litigation?

MR. KOTT: Object to the form.

THE WITNESS: As an expert opinion for this client who was a patient of mine for a time --

BY MS. MOORE:

Q. And had no complaints?

MR. KOTT: Object to the form. Object to the interruption.

THE WITNESS: With regards to when she got involved with litigation, I have no idea, so I can't judge on when that happened. As a clinician when she came to see me on November 19th, I have to take what she tells me as the truth. I can't sit here and go, hey, is this litigation induced? I did not know that. My

job is to see her at that point. Listen to her, write down what she reported to me. Examine her, write down what I saw. Okay. Now, so in reference to the reference here, as an expert for this patient, it's what I saw versus also in contrast and encompassing what others saw through the extended time frame of which I did not see her or in conjunction of when I may have seen her as well.

BY MS. MOORE:

Q. Tell me about the time you did see her when there were no complaints.

MR. KOTT: Objection to the form.

THE WITNESS: I think I already answered that, where I said did not document vaginal discharge.

BY MS. MOORE:

Q. Or pain or any of these things, right? During the time you saw her -- up until, let the record be clear, up until November 19th, 2015, when you treated Mrs. Morrow, there was no evidence of bleeding until the last visit, no evidence at all of the vaginal discharge. No evidence of pelvic and groin pain. No evidence of burning in groin area --

in the groin area, correct?

MR. KOTT: If you include one thing, I won't object: On his records.

MS. MOORE: I will include that.

MR. KOTT: Thanks.

BY MS. MOORE:

Q. This is only on your records and your care and treatment.

MR. KOTT: It's been answered.

THE WITNESS: As I mentioned, and that is correct. When you take, then, in the other visits, etcetera, between that time frame, correct.

BY MS. MOORE:

Q. Okay. So --

MR. KOTT: Come on.

BY MS. MOORE:

Q. -- the intensity of the pain progressed. That's, again, based on what she's telling you?

A. That's correct.

MR. KOTT: Object to the form.

BY MS. MOORE:

Q. During the time you treated Mrs. Morrow, did she ever report -- outside of this most recent

visit again in --

MR. KOTT: November 2015.

MS. MOORE: -- November 2015 --

BY MS. MOORE:

Q. -- did she ever complain of a chronic urinary tract infection?

A. When she was with me, again, just review encompasses all the visits. But when she was with me, there was none documented, correct.

Q. Okay. You mention rheumatoid arthritis, are you attributing that to the mesh product?

A. That was something she brought up to my attention, the new diagnosis of rheumatoid arthritis, and I'm just simply stating it's a new significant diagnosis.

Q. And are you attributing that to the mesh product?

A. There's a chronic inflammation stated in this situation. I'm just stating she has a new diagnosis. She has a chronic inflammatory condition. I'm not making any conclusions.

MS. MOORE: Let's go off the record -- back on for a second.

VIDEOGRAPHER: Okay. We are going off the

record. The time is 11:28.

(Off the record.)

VIDEOGRAPHER: We are back.

BY MS. MOORE:

Q. Let me know, sir, what complaints, if any, that Mrs. Morrow is complaining of that you would attribute to the Ethicon device? And as you go through that, I want to know if you're talking about the Prolift or the TVT.

A. Okay.

MR. KOTT: As of this current state of knowledge or just on his records?

MS. MOORE: As an expert.

MR. KOTT: As an expert.

THE WITNESS: Involving all of the information, not just when she saw me?

MS. MOORE: Yes, sir.

MR. KOTT: Thank you.

BY MS. MOORE:

Q. Your whole collective constellation.

A. The bleeding and the pain. Obviously the intensity is an added adjective to describe it. Obviously the dullness as described it. Sharpness is a description of it. The limitation of the

exercise due to the pains. She comments that even walking is painful. Simple daily activities or quality of life issues, such as working around the house, yard, bending, squatting is intolerable. The recurrent erosions. The granulation tissue. The repeated interventions and surgical revisions required. The -- again, the transaction of the mesh arms there. Again, what she described as chronic urinary tract infections. The splinting that occurred with constipation. And the bowel movements with vaginal bleeding. In terms of her symptom complaint, that is what I would attribute to the mesh.

Q. Okay. And just quickly go through these. You are aware that bleeding would be a risk of any surgery with or without mesh?

A. Yes.

Q. And you were aware that pain, as outlined in your consent forms, could be a risk of any surgery with or without mesh?

A. Yes.

Q. Pain can, of course, limit one's activities, you're aware of that?

A. Correct.

Q. Erosion, you were aware of the risk of erosion. We have discussed and debated the range. Your experience was higher than what you say was reported to you by Ethicon, but nonetheless you were aware that that could occur, correct?

A. Also included in the literature, but yes, correct.

Q. You were aware that granulation tissue is a natural response to healing with or without surgery?

A. I wouldn't describe it as a natural process, no.

Q. It is a response that can occur from surgery?

A. But in this case with a mesh, which is a post-hyperaggressive inflammation, it's going to be more predisposed to cause a patient to have that type of reaction.

Q. You were aware, as a surgeon, that granulation tissue could occur in a surgery with or without mesh, correct?

A. Correct.

Q. You were aware that there could be failure of an outcome or a necessary reason to repeat the

surgery?

A. Correct.

Q. And have a repeat of the underlying condition that warranted the surgery?

A. Correct.

Q. You were aware of the risk of infection, including the risk of UTI?

A. Correct.

Q. You were aware that there could be bowel problems as a result of surgery?

A. Correct.

Q. Now, in all the things we just discussed, you were aware, before you did surgery with any of the patients that we have talked about thus far, Mrs. Shively, Ms. Taylor, Ms. Goodyear, and as we turn to -- in a few minutes --

A. My wife wasn't involved in this.

MR. KOTT: You said Ms. Goodyear.

BY MS. MOORE:

Q. My apologies.

A. That's okay.

Q. You were aware of all these risks --

MR. KOTT: For all the patients involved.

MS. MOORE: Thank you very much.

MR. KOTT: You're welcome.

BY MS. MOORE:

Q. For all of these patients, for Mrs. Shively, Ms. Taylor, Mrs. Morrow, and as we are about to discuss this afternoon, Ms. Bennett, correct?

A. I was aware that there were risks.

Q. That could occur with mesh surgeries, and as we said yesterday, even without mesh surgery?

A. Not the erosion. Because you have no -- if you're doing a posterior colporrhaphy, anterior colporrhaphy there's nothing to erode. So the erosion --

Q. There are mesh surgeries with other types of grafts, with porcine and with cadavers, correct?

A. And that is correct.

Q. And with sutures?

A. Yes. That is correct. But sutures are typically --

MR. KOTT: Whoa, whoa, let him answer.

BY MS. MOORE:

Q. Move to strike. You were aware that that could occur with other surgeries outside of mesh, correct?

A. But the sutures will dissolve. But, yes, to answer your question specifically, the answer is yes.

Q. Thank you. And then, finally, when doing your differential diagnosis that you discussed --

A. So we moved on to methodology?

Q. Yes, please, turn back to that, if you don't mind. How were you able to rule out that the vaginal discharge being caused by any of the other potential items listed on page four of your report?

A. The listing of the differential diagnosis here is including all possibilities.

Q. Yes, sir.

A. So I guess I'm not understanding your question.

Q. So in determining -- did you determine that her vaginal discharge that you never noted -- in your treatment of her -- was related to the mesh?

MR. KOTT: Object to the form.

THE WITNESS: Okay. Can you re-ask that question again, I'm sorry?

BY MS. MOORE:

Q. Sure. You have down here under methodology --

A. Yes.
Q. -- possible -- you say "made a differential of the possible causes of Tina Morrow's postoperative issues" --
A. Correct.
Q. -- "and the relationship to the mesh, if any." You say "vaginal discharge." That is something that you did not see or she did not complain about during the time you treated her?
MR. KOTT: Object to the form.
THE WITNESS: Until she followed up on November 19th?
BY MS. MOORE:
Q. Yes, sir. Until she followed up?
A. Correct.
Q. And so are you attributing her complaint of vaginal discharge to you in November of 2015 to the mesh?
A. I am.
Q. And what allowed you to land on the mesh, to pick the mesh as the problem or the reason for the discharge, despite that she had other potential causes?
MR. KOTT: Object to the form.

THE WITNESS: She had recurrent erosions, recurrent surgical resection required. So it showed itself to be a persistent problem.

BY MS. MOORE:

Q. You ruled out the atrophic vaginitis?

A. As the primary cause.

Q. And so atrophic vaginitis can cause discharge?

A. Yes, but does not cause erosion.

Q. I'm not talking about erosion, sir, I was asking about vaginal discharge.

A. Yeah, but the erosion causes the vaginal discharge.

Q. Okay. I'm talking about causes for vaginal discharge. Is erosion the only thing that can cause vaginal discharge?

A. No, but she has the recurring vaginal mesh erosion.

Q. And she also has an atrophic vaginitis, did that go away?

A. It did not, but she was --

Q. Is that recurring?

A. But she was on therapy for it too.

Q. If the records indicate that --

A. When she saw me and I documented in my charts, where there was no vaginal discharge, I had her on -- majority there on vaginal estrogen.

Q. And if the records indicate that she was not taking the Estrace, would your opinion differ on the possible cause of the vaginal discharge?

MR. KOTT: Object to the form.

THE WITNESS: No, because of the mesh erosion.

BY MS. MOORE:

Q. No matter what I say you're going to say mesh, mesh, mesh?

MR. KOTT: Form.

THE WITNESS: When you look at issues, there's always going to be primary problems. And there's going to be secondary. So the primary issue here, the culprit, is the mesh exposure that is recurrent.

BY MS. MOORE:

Q. Okay. And then she's menopausal too, is that --

A. That is correct.

Q. And do menopausal women sometimes have vaginal discharge?

A. That is correct.
Q. Did that play --
A. I'm sorry up. Back up, ask that question again.
Q. Can menopausal women have vaginal discharges?
A. Yes, they can.
Q. So that did not play a role at all you think?
A. The atrophic vaginitis postmenopausal state?
Q. Those other two conditions that may cause vaginal discharge did not play a role in the vaginal discharge that Mrs. Morrow referenced to you in November of 2015?
A. As I referenced yesterday, most women will have a discharge and it varies from -- during the cycle, that's pretty normal. Process of fertility is involved there as well. But when you look at the discharge that when a woman moves beyond menopause because of the hormone deficiency state, you actually see a significant decline in the vaginal discharge. And that's one of the issues associated with some of the increased risk for vaginal

infections and UTIs that are associated, because you have a decreased vaginal discharge because of altered vaginal floor associated with the declining hormones that are associated here. So if you take that in context, what we are dealing with here is a mesh erosion that's recurrent. A vaginal atrophic -- atrophic vaginal mucosa, which should preclude the patient to a decline in vaginal discharge, but we are actually seeing an increase.

Q. Move to strike as non-responsiveness.

Do you have any literature at all to support your differential diagnosis on vaginal discharge, is that referenced in your reliance list?

A. The reference in the reliance list as it pertains to the mesh Prolifts, TVT-O.

Q. Now, let's move to -- so the answer is no?

MR. KOTT: Objection to the form.

THE WITNESS: It's not specifically labeled there as such.

BY MS. MOORE:

Q. Let's go to dyspareunia. And throughout the entire time that Mrs. Morrow saw you up until -- until November '15, she did not complain of any pain with sexual intercourse, correct?

A. In my office visit, she herself did not complain, correct.

Q. And you testified that atrophic vaginitis can cause pain or discomfort with sexual relations, intercourse?

A. It can be due to vaginal dryness and decreased lubrication.

Q. You discounted that and in your opinion, it's the mesh here?

A. Again, what I said, as you process through menopausal transition, the decline in the vaginal discharge, that mucus is very important for lubrication and moisture involved in the vaginal mucosa to receive the act of intercourse. So you remove that, then you have the decrease in the lubrication, you're going to get more tearing and shearing as it relates to that very thin mucosa. So it's not likely that that is the process involved there.

Q. And so your -- despite that she never during the time you treated her until November of 2015 complained of pain with sex, you are going to say that any pain she may have with sex is related to the mesh, fair enough?

MR. KOTT: Objection to the form.
MS. MOORE: I'll withdraw it.
MR. KOTT: If you can rephrase it.
MS. MOORE: I'll withdraw it.
BY MS. MOORE:
Q. It's your opinion that if she's having pain with sex, it's a result of the mesh?
A. Because of the recurrent vaginal mesh exposure, correct.
Q. And pelvic pain, she never complained of pelvic pain to you during the time you treated her up until November of 2015 and she was involved in the litigation, right?
MR. KOTT: Object to the form.
THE WITNESS: Again, the time that I saw her during the immediate postoperative period and the follow-up thereafter, she did not complain of that. But beyond that she did, and I included that in her summary when she came back.
BY MS. MOORE:
Q. So you now say, okay, pelvic pain, that's going to be caused by the mesh?
MR. KOTT: Object to the form.

BY MS. MOORE:

Q. Anything she tells you -- anything she says you accept as being caused by the mesh?

MR. KOTT: Object to the form.

THE WITNESS: She has a recurrent vaginal mesh exposure.

BY MS. MOORE:

Q. And that's causing all the problems that Mrs. Morrow is experiencing?

MR. KOTT: Object to the form.

THE WITNESS: As it relates to the pelvic pain and vaginal bleeding and the discharge, etcetera, yes.

BY MS. MOORE:

Q. And walking?

A. It is the foci of chronic inflammation. Without it being there, there would be no foci for that presence, which is part of the issue related to this product, the safety and efficacy.

Q. Vaginal bleeding. I think we have talked a lot about the bleeding.

MR. KOTT: Yes, we have.

BY MS. MOORE:

Q. And despite the fact she had other possible causes of the vaginal bleeding, being postmenopausal and having atrophic mucosa, you have discounted that and said, if she tells you that it's caused by the mesh, you're going to agree with that?

MR. KOTT: Object to the form.

THE WITNESS: Again, she had a recurrent vaginal mesh here, this is the primary foci of the chronic vaginal bleeding and discharge because of the chronic inflammatory response.

BY MS. MOORE:

Q. That's your methodology, right? Anything else you want to add to your methodology?

A. I think we covered that yesterday and today.

MS. MOORE: I don't know if I have time left; but if I do, I will save it for rebuttal.

VIDEOGRAPHER: Yes, you have about 15 minutes.

MS. MOORE: Thank you so much.

MR. KOTT: Thank you. Thank you.

(Off the record.)

VIDEOGRAPHER: We are off the record. The time is 11:52.

MS. KOTT: Hang on a second.

VIDEOGRAPHER: I'm sorry.

(Off the record.)

VIDEOGRAPHER: We are on. 11:57 a.m.

EXAMINATION

BY MR. KOTT:

Q. Doctor, as you know, my name is Joseph Kott. And one of the plaintiffs that I represent in this matter, amongst others, is Mrs. Tina Morrow.

A. Correct.

Q. Okay. And also, so I speak clear, you were her treating doctor for a period of time, correct?

A. Correct.

Q. And also I retained you as an expert witness in this matter too; is that correct?

A. Correct.

Q. An article came up this morning regarding the percentages -- the percentages that you put in your report -- excuse me, in your notes and the record, for some reason, seem to be very much discussed in this process; is that fair to say?

A. Fair to say.

Q. And you pulled up one such article that

shows about 4.7 percent, not about, actually shows a 4.7 percent of mesh exposure; is that correct?

A. That is correct.

Q. And that's labeled with Bates number --

A. Deposition Exhibit No. 55.

Q. Excuse me, I meant to say deposition exhibit. And, Doctor, would you recite the title of this article?

A. "Transvaginal Repair of Genital Prolapse: Preliminary Results of a New Tension-free Vaginal Mesh, Prolift Technique, a case series multicentric study."

Q. Thank you. Now, do you recognize -- would you please just put on the record the name of the authors of this article?

A. I may mispronounce them. Fatton, Amblard, Debondinance, Cosson, and Jacquetin.

Q. Did you recognize any of those names?

A. I recognize the last two.

Q. What about those names jogs your memory as to knowing who they might be?

A. They were involved in the original TVM procedures in France that originally came over and came forth to the Ethicon Prolift product.

Q. Okay. Do you know if there was a patent held by any of those two people on the TVM material?
A. Yes, they hold the patent.
Q. Do you know if one of those persons sold the patent to Ethicon?
A. I do know that.
Q. Which one of those was it?
A. Jacquetin.
Q. Thank you. So is it fair to say that this information that you discussed this morning regarding the reported percentage of 4.7 percent was promulgated by people -- physicians closely affiliated with Ethicon?
MS. MOORE: Object to the form of the question.
THE WITNESS: That's correct.
BY MR. KOTT:
Q. Pretty obvious?
A. Very obvious.
MS. MOORE: Same objection.
MR. KOTT: I'm going to, just for the sake of completion, to attach as Exhibit No. 64, the Cross Notice, like we do. I'm going to put that right here to keep it there.

MS. MOORE: No worries.

(Exhibit No. 64 marked.)

BY MR. KOTT:

Q. Okay. Now, Doctor, we have an in globo exhibit that has been numbered as Exhibit No. 66 in this --

MS. KOTT: Should be No. 65.

MR. KOTT: That should be No. 65. And we are going to change it to No. 65 momentarily. Thank you.

(Exhibit No. 65 marked.)

BY MR. KOTT:

Q. Doctor, and I'm going to ask you to please look through these. There are three separate, for lack of a better term, we'll call them brochures. If you will look at those three terms -- maybe it's the best "brochures."

A. Yeah, they are the brochures that I'm familiar with as it relates to these products.

Q. And those brochures were given to you -- who gave those brochures to you when you were practicing in this capacity as an operating gynecologist?

A. The Ethicon representative would have

given them to me.

Q. May I see those, please? And, Doctor, also I've been reminded by my colleague, the brochures from Ethicon are referenced in your reliance list -- in your report. Excuse me?

A. Yes, that's correct.

Q. Thank you. And were these what you provide to patients or put in your office in some fashion for patient review?

A. Yes.

Q. Okay. And were those in your office the times that you performed the surgery on the four patients subject to this -- let me finish -- subject to this deposition process?

MS. MOORE: Object to the form.

THE WITNESS: The Ethicon pamphlets available at that time were in my office as it relates to the TVT products and the Prolift, correct.

BY MR. KOTT:

Q. Thank you. And where is the front page to No. 66? No. 65. Thank you.

Doctor, I'm going to show you another brochure that I'm going to again -- another document

that is multipage, it's Bates numbers 8003247 through 3262, and ask you if you would identify this? I will, again, categorize it as a brochure for the TVT.

A. That is correct.

Q. Doctor, do you recognize that?

A. Yes, I do.

Q. Doctor, is that a brochure that would have been like the others provided by Ethicon through the sales rep?

A. Correct.

Q. And was that one that was in your office during the periods relative to this case?

A. Bonnie Blair, TVT brochures of many different varieties were very, very common in our office.

(Exhibit No. 66 marked.)

Q. Thank you. And that's No. 66. Exhibit No. 66. Doctor, in relation to the previous questioning about what symptoms Mrs. Morrow was distributing -- exhibiting and what complaints she had in November of 2009 as reflected in your office, do you remember those questions?

A. I do.

(Exhibit No. 67 marked.)

Q. Doctor, I'm going to show you what we have marked as Exhibit No. 67, which is a three-page document. And I'll tell you it's from a Dr. Bobby Ensminger.

A. Ensminger, yes.

Q. Do you recognize that doctor's name?

A. I do.

Q. How do you know about this doctor?

A. We actually went to medical school together.

Q. Okay. And did he also see Mrs. Morrow in November of 2009?

A. Correct.

Q. And what was her chief complaint with Dr. Ensminger?

A. Dr. Ensminger, correct. She complained of abdominal pain, constipation, diarrhea, vaginal bleeding.

Q. Okay.

A. And migraine.

(Exhibit No. 68 marked.)

Q. Thank you. Next document number is No. 68, it is a two-page document -- three page, excuse

me, I'll purport that it is a medical record from Dr. Landon Smith. Is that --

A. That is correct.

Q. And what date did Dr. Smith see Mrs. Tina Morrow?

A. That was November 13th, 2009.

Q. Okay. And would you record -- is that about the same time you had seen her in that November 2009 period?

A. It was in close proximity.

Q. Would you record the complaints made to Dr. Smith at that time?

A. Female, she presents with dyspareunia, vaginal discharge, dyspareunia and dysuria. Patient states that her bladder tacked up and thinks that may be the source of the pain.

Q. Thank you. And, Doctor, we have marked this as Exhibit No. 68. And, Doctor, when you prepared your report in this case, is it fair to say that you had access to these medical records in addition to your own?

A. Correct.

Q. Okay. When you refer to the vaginal bleeding, the dyspareunia, the discharge, dysuria,

that Mrs. Tina Morrow complained of, you had access to these other doctors' records too, correct?

A. That is correct.

(Exhibit No. 69 marked.)

Q. Okay. I have another document here that is No. 69, and it is also Bates numbered 5 through 23. We have different Bates number systems, but this is in globo Exhibit No. 69. I'll give this document to you.

And, Doctor, would you tell us the date on this document?

A. January 26th, 2010.

Q. And who is this doctor?

A. It's a Dr. Robert L. Harris.

Q. Do you know that doctor also?

A. I do not know him personally, but I know of him.

Q. And in January 2010, if you would look in the history of the present illness in 2010, January 26th, does she report to Dr. Harris that she continued to bleed, in the fifth line down or sixth line down?

A. "She had mesh exposed anterior and posterior. Patient states she now feels pelvic

pressure like prolapse returned. Some symptoms of urinary urgent incontinence and does have feelings of IBE." I'm not sure what that is. As well as intermittent urinary urgent incontinence, stress urinary incontinence." Yes, here we go. When she attempted intercourse, her husband again felt mesh and she continued to bleed.

Q. Thank you. Were these records available to you when you prepared your report?

A. They were.

Q. Thank you. And that's No. 69.

So in your report when you're saying she's having all these symptoms, while she did not have those symptoms -- she did not complain of those to you, contemporaneously she was being seen by other physicians for those symptoms?

A. That is correct.

Q. Thank you. And you incorporated that information in your report, correct?

A. That is correct.

MS. KOTT: Can we go off the record for a second?

VIDEOGRAPHER: Time is 12:09.

(Off the record.)

VIDEOGRAPHER: Okay. We are going back on the record. 12:09.

(Exhibit No. 70 marked.)

BY MR. KOTT:

Q. Doctor, I'm going to show you an in globo document of -- I see. So it's three. No. 70. And ask you if you would look at this document, please, from 2015?

A. Correct.

Q. Do you see who the author of this document is?

A. Dr. Winters. Jack Christian Winters.

Q. Did you review Dr. Winters' notes also in your preparation of your report?

A. I did.

Q. Okay. And in Dr. Winters' notes, did he recommend surgery to her ultimately in his care for her?

A. He did.

Q. Okay. Thanks. All right. That's enough. I've got stuff to do.

Now, Doctor, you were asked questions to show that any surgical procedure has risks, correct?

A. Correct.

Q. And you went through a long list of surgical risks with Ms. Moore?
A. Morrow.
Q. No, I was thinking Kim. You did?
A. Yes.
Q. Now, Doctor, you knew all these risks existed when you did the surgery on all these patients; is that correct?
A. Correct.
Q. Is the point that you're making that those risks had been underestimated in educating you by the manufacturer?
MS. MOORE: Object to the form. Move to strike the leading question.
THE WITNESS: The point I'm making is that the procedure and the mesh, the device itself, underestimated the risks as well as the benefits.
BY MR. KOTT:
Q. Did they underestimate the benefits or overestimate the benefits?
MS. MOORE: Same objection.
THE WITNESS: They overestimated the benefits.

VIDEOGRAPHER: We just crossed three hours.

MR. KOTT: You have to keep track of my time, I had 30 minutes.

VIDEOGRAPHER: That's right. My apologies. I am keeping track.

BY MR. KOTT:

Q. In Mrs. Morrow's case, based upon the extensive detailed review you did of your records with Ms. Moore, it seems like in your view she had had -- she thought she had recovered to a certain degree from the initial surgery; is that fair to say?

A. That's correct.

Q. And it seems like some time later she started developing the serious problems for which she was treated by other physicians; is that correct?

MS. MOORE: Object to the form. Leading.

THE WITNESS: Along with the recurrent mesh exposure, that is correct.

BY MR. KOTT:

Q. And does that fit with the medical paradigm that one sees when there are complications

from mesh erosion?

MS. MOORE: Same objection. Object to the form. Object to the leading nature of all these questions.

THE WITNESS: The literature clearly describes a continuous ongoing chronic inflammatory nature state as it relates to the mesh insertion, with a continued increase exposure rate as you progress from the time of surgery.

BY MR. KOTT:

Q. Is that what happened in Mrs. Morrow's case?

MS. MOORE: Same objection.

THE WITNESS: That's correct.

BY MR. KOTT:

Q. Now, Doctor, let's go to your report, if we could.

A. Okay.

Q. Doctor, you have gone through your methodology in part with Ms. Moore, correct?

A. Correct.

Q. You also listed opinions; is that correct?

A. That is correct.

Q. And you have at the top on page six that, "all opinions given to a reasonable degree of medical probability"; is that correct?

A. Correct.

Q. Can we also apply the standard of medical certainty?

A. Correct.

Q. Doctor, you were asked earlier about a term you used in one of your consent of probability. Do you remember that?

A. I do.

Q. Okay. Would you tell the Court the distinction between the concept of statistical probability used in a scientific term versus what you know of the legal term "probability," that you have learned in this work?

A. The probability as it relates to statistical medicine is that you are excluding the opportunity of chance involved in the issue in question.

MS. MOORE: Objection.

BY MR. KOTT:

Q. Okay. And you learned that there's a different meaning attached to that in the law,

correct?

MS. MOORE: Objection.

THE WITNESS: I don't know. But as it relates to the science, this is what I do know.

MR. KOTT: Thank you.

If you want to put an objection on, you can.

MS. MOORE: I did.

BY MR. KOTT:

Q. Okay. And you were using that as a scientific term, correct?

A. That is correct.

Q. Thank you. Doctor, I noticed during the course of the deposition you have a little bottle that you have a -- drops that you put in your water?

A. Peppermint.

Q. What is that?

A. It's peppermint. It's an essential oil.

Q. Okay. Thank you. The other question I had. Did you receive -- did you ever get any instruction from anybody, from the rep, the doctors involved that you should not use these products on patients that are obese?

A. No. In fact, they encouraged us that this

would be a more minimally invasive procedure, and it would be better tolerated than -- versus an abdominal sacral colpopexy or abdominal approach. So it was actually advocated as a safer alternative.

Q. Now, Doctor, back to your opinions on page six. Would you tell me your opinion expressed in item number one?

A. "Tina Morrow's injuries were caused by the implanted Prolift and TVT-O devices."

Q. Okay. Doctor, you go on after that item to have several paragraphs supporting those opinions; is that correct?

A. That is correct.

Q. Doctor, is -- are those paragraphs -- now that you look at them, are you willing to under oath assert those paragraphs as the bases for your opinion, item number one?

A. Yes.

MS. MOORE: Object to the form. I don't want to keep interrupting, but I want to note my continuing line of objection to form and leading with respect to these questions.

MR. KOTT: Okay. Well, let's put this on the record. Because of the nature of this

deposition, plaintiff is given one half hour to question this witness. This is characterized as a discovery deposition, and the only way to get any evidence on in this matter, practically for the plaintiff, is to ask leading questions. And we'll deal with that at a later time.

MS. MOORE: Same objection.

BY MR. KOTT:

Q. Item number two in your report.

A. Yes.

Q. What was your second opinion?

A. "The Prolift and TVT-O devices implanted in Tina Morrow were unreasonably dangerous due to the lack of adequate warning."

Q. And, Doctor, you go on in subsequent paragraphs to establish the bases for that opinion; is that fair to say?

A. That's correct.

MS. MOORE: Same objection.

BY MR. KOTT:

Q. Under oath, do you assert that those -- bases for that opinion are, in fact, those that you have used to support conclusion two?

A. Correct.

Q. Now, Doctor, right above conclusion two on seven -- page seven, you have, "safer alternatives were available that are equally effective"; is that correct?

A. Correct.

Q. What were those safer alternatives for Mrs. Morrow?

A. That would be observation, that would be pessary, surgical procedures were to be including non-mesh implants such as anterior/posterior colporrhaphy. They could include a sacrospinous fixation. They could include abdominal sacral colpopexy. The safer the alternatives would be the observation, the pessary, and then the non-mesh of the anterior/posterior colporrhaphy.

Q. And what about the TVT, were there alternatives to doing the TVT, the sling?

A. There are alternatives to the TVT. You can use pessaries, you can use biofeedback. You can use Kegel exercise. You can even use vaginal estrogen.

Q. Now, did we do item three? Yes, we did.

A. No, we have not done.

Q. Please do item number three. Your opinion

three.

A. "The Prolift and TVT-O implanted in Tina Morrow were unreasonably dangerous because they did not conform to the manufacturer's express warranty."

Q. Okay. And, again, you go on for a page or two, a page and a half, expressing the bases for that opinion; is that correct?

A. That is correct.

Q. And under oath is it fair to say that you assert that those are your bases?

MS. MOORE: Same objection.

THE WITNESS: That is correct.

BY MR. KOTT:

Q. Let's go to those bases, Doctor. Item A, you are here, the Prolift mesh was soft?

A. Correct.

Q. Was the Prolift mesh after it had been implanted for a period of time soft?

A. It was not.

Q. This is something that the manufacturer had asserted, correct, that it was soft?

MS. MOORE: Object to the form of the question.

THE WITNESS: That it was a soft mesh,

correct.

BY MR. KOTT:

Q. Okay. Item B -- what was Item B that you felt the manufacturer did not meet an express warranty?

A. The Prolift allowed for the restoration of sexual function by restoring normal vaginal anatomy.

Q. Manufacturer asserted that?

A. They did.

Q. Was that true?

MS. MOORE: Object to the form.

THE WITNESS: That is not true.

BY MR. KOTT:

Q. Item C, "many patients return to normal" -- would you read Item C?

A. "Many patients return to normal daily activities within three to four days, most completely recover within a two- to three-week period."

Q. Was that true?

MS. MOORE: Object to the form.

THE WITNESS: Not even close.

BY MR. KOTT:

Q. What about D, "risks are rare and small"?
MS. MOORE: Same objection.
THE WITNESS: Completely untrue.
BY MR. KOTT:
Q. Item E on page nine, would you read that into the record?
A. "The Prolift is appropriate for almost all patients, including patients who are overweight, elderly or have undergone pervious surgeries for pelvic organ prolapse."
Q. Was that true?
MS. MOORE: Objection.
THE WITNESS: No. And I alluded to that earlier, that it was advocated as a safer alternative by the company.
BY MR. KOTT:
Q. Item A is the next Prolift item, would you read that into the record?
A. "The mesh elicits a minimum to slight inflammatory reaction is transient."
Q. The manufacturer asserted that?
A. They did.
Q. Was that correct?
A. That isn't.

MS. MOORE: Object to the form.

THE WITNESS: That is not correct. And studies have shown that it is an ongoing chronic inflammatory process.

BY MR. KOTT:

Q. We could go down this entire list, but is it fair to say that on your report, that entire list, you swear to those as your opinions?

MS. MOORE: Same objection.

THE WITNESS: I do.

BY MR. KOTT:

Q. And we'll get a chance to do that but not in this setting.

Now, Doctor, did the mesh cause the symptomatology that you -- and problems and need for surgery that you itemized in your report? Did the mesh cause those problems in Mrs. Morrow?

MS. MOORE: Objection.

THE WITNESS: They did.

BY MR. KOTT:

Q. Did the failure to warn about the risks and the failure to meet the express warranties of the product, did they lead to the use of the mesh by you?

MS. MOORE: Object to the form.
THE WITNESS: They did, and I would have never used it if I'd otherwise known correctly.
BY MR. KOTT:
Q. So you would have not used this product on Mrs. Morrow if you had had the actual risk and knew that the warranties were not going to be met?
MS. MOORE: Objection.
THE WITNESS: That is correct.
MS. KOTT: Can we go off the record?
MR. KOTT: Yeah, let's go off the record for a second.
VIDEOGRAPHER: Going off the record. The time is 12:21. You have six minutes.
(Off the record.)
VIDEOGRAPHER: We are back on the record, 12:22.
BY MR. KOTT:
Q. Okay, Doctor. When you took courses from Ethicon, they taught you the appropriate level at which you should position the mesh and TVT in the submucosa tissue?
MS. MOORE: Object to the form.
THE WITNESS: That is correct.

BY MR. KOTT:

Q. And you always did that?

A. Correct.

Q. And in Mrs. Morrow, there was some comment on pelvic examination about banding and the arms?

A. That is correct. The banding or the arms related to the Prolift create contracture with a chronic inflammatory state, and is a foci for pain. So that could -- likely did and likely contributed to her dyspareunia and pelvic pain that she noted.

Q. In addition to the erosion?

MS. MOORE: Object to the form.

THE WITNESS: Correct.

BY MR. KOTT:

Q. Doctor, in the warranty section -- if you go back to the warranty on your report, you have a number of things in quotes. Can you see that as we go through the list there in quotes?

A. Yes.

Q. Soft is in quotes. Many things; is that correct?

A. That is correct.

Q. Why are they in quotes?

A. Because they are the words from Ethicon.

Q. And where did you find all those words?
A. These were in the brochures or IFUs.
Q. So you did not make those up, that's actual language you saw in these documents?
A. That is correct.
Q. And -- I'll withdraw that start of the question. Go back to my notes here.
Doctor, you were asked if you had looked at any specific literature in forming your list of differential diagnoses in the methodology section. Do you remember that?
A. I do.
Q. Doctor, how many books have you read in gynecology about the causes of vaginal pain?
MS. MOORE: Object to the form of the question.
THE WITNESS: Many, many.
BY MR. KOTT:
Q. How many books in gynecology have you read about infection?
MS. MOORE: Same objection.
THE WITNESS: Many, many.

BY MR. KOTT:

Q. And how many articles?
MS. MOORE: Same objection.
THE WITNESS: Too many to count.
BY MR. KOTT:
Q. So while you did not do any specific -- necessarily any specific literature research for your differential, but there's a body of study that you have done about differential; is that fair to say?
MS. MOORE: Same objection.
THE WITNESS: That is correct.
MS. KOTT: Can we go off the record for a second?
VIDEOGRAPHER: Sure. 12:25.
(Off the record.)
MR. KOTT: We are back on the record.
BY MR. KOTT:
Q. I just have one -- I think one loose end to clear up. The email this morning about whether you were at the meeting in 2007 in Utah and you said it was 2008? Do you remember that?
A. I did.
Q. It's clear in your mind it was 2008?
A. Correct.

Q. Did you mean to deceive anyone or anybody or anything by saying it was 2007 yesterday?

MS. MOORE: Object to the form.

THE WITNESS: No. Just miscited the year, that's all.

BY MR. KOTT:

Q. All right. Doctor, you were asked a number of questions this morning for close to three hours regarding your opinions in this case, and other things; is that correct?

A. That is correct.

Q. Doctor, based on that question, has that questioning changed any of the opinions that you have expressed in your report?

A. Absolutely not.

MR. KOTT: Thanks. I'm done.

MS. MOORE: Quick switch and we'll knock this out.

VIDEOGRAPHER: I'm off.

(Off the record.)

EXAMINATION

BY MS. MOORE:

Q. Let's look at Exhibit No. 67. A visit by Mrs. Morrow to Bobby Ensminger.

VIDEOGRAPHER: You want to go on?

MS. MOORE: Catch me if you can.

VIDEOGRAPHER: We are on. 12:28.

THE WITNESS: No. 67?

BY MS. MOORE:

Q. Yes, sir.

A. Okay. Do you have that in front of you? I don't.

Q. Yeah, this is my -- I bet it's here. Are we on the record?

VIDEOGRAPHER: We are on the record.

MR. KOTT: Wait, here it is. There's No. 67.

BY MS. MOORE:

Q. Exhibit No. 67, which is an office visit Mrs. Morrow had with Dr. Bobby Ensminger, looks like the date is November 10th, 2009?

A. That is correct.

Q. And if you review further down, under HPI, she says, "have seen Goodyear once and wants another opinion." Do you know why she was seeking another opinion outside of yours?

A. No clue. I wasn't there, so I don't know.

Q. In the care of Mrs. Morrow, the TVT was

used to address any problems with stress urinary incontinence, correct?

A. Correct.

Q. And as you sit here today, she does not have problems with stress urinary incontinence, correct?

A. According to my last exam, she does not complain of stress urinary incontinence.

Q. So would it be fair to say that the TVT performed its intended function and assisted her in eliminating any stress urinary incontinence complaints?

A. Per my last visit, that would be correct.

Q. And in your report, you don't address or attribute any stress urinary incontinence to the TVT, correct?

A. I'm sorry?

Q. In your report, you do not attribute any problems with stress urinary incontinence to the TVT, correct?

A. Are you asking me if I'm attributing -- if I'm saying that in the report that the TVT corrected her stress urinary incontinence or the post -- post the TVT-O that her stress urinary incontinence

resolved?

Q. Good point. Did the TVT correct her stress urinary incontinence?

A. The symptoms she came in with and basically up to this point, that is correct, that has resolved.

Q. You talked a little bit about inflammation, and inflammation is something you have actually researched, correct?

A. Correct.

Q. Recently researched it. And you published on it in the sense of blogging on it?

A. It's an ongoing process, it is critical in any chronic disease of aging, so looking at any preventative process, it has to be a part of that.

Q. And it's your opinion in this case that the mesh caused some type of inflammatory response in Mrs. Morrow?

A. It's a foci of a foreign body which creates a foreign body reaction which is an inflammatory reaction. When you put a foreign body in the body, what happens is the body creates an inflammatory reaction to it, tries to wall it off, and that process then develops the ongoing process

that you see in these chronic issues associated with mesh, including the contraction, mesh erosion, etcetera.

Q. So you are, at least in this instance, saying that Mrs. Morrow's inflammation would be caused solely by the mesh? If she's having any inflammation, it's caused by the mesh?

A. Well, as it relates to the vagina if that mesh was not put there, there wouldn't be that external foreign body, so to answer that, yes.

Q. Now you have talked and published recently that there are many causes of inflammation, correct, many sources?

A. There are many sources, correct.

Q. And you talk about obesity being one?

A. Correct.

Q. Was Mrs. Morrow obese?

A. She was.

Q. Okay. Could her obesity contribute to inflammation?

A. Oh, it does.

Q. How come you did not report on that or discuss that in your report?

A. I don't know that I mentioned the mesh

creating a -- being the foci of inflammation, did I?

Q. I thought you discussed it today, and you did reference the ongoing problem that Mrs. Morrow has had with her obesity.

A. Because this deposition was with regard to the placement of the mesh.

Q. All right. And just so you know, I don't want to limit it to just the placement of the mesh. I want your opinion on Mrs. Morrow, and that includes anything and everything about her that may play a role in the conditions that we are discussing, and more importantly, the conditions that you are saying are caused by the mesh.

A. And I understand that. But I have to be very careful not to pretend to know what you're thinking, that you want me to answer as it relates to the questioning.

Q. I'll try to be clearer for you. We are talking about inflammation. What type of -- how would you qualify her obesity?

A. Her last weight here on November 9th, 2015, was -- BMI 43.8. That would be morbid obesity.

Q. And she's had that condition since you

first started treating her?

A. Here on the initial visit, which is June 11th, her BMI was 41.8. So, correct, those both meet that qualification.

Q. So you said the inflammation is related to the mesh?

A. As it relates to the vagina, that is correct.

Q. Could her morbid obesity, that you discuss on your blog that causes inflammation, also cause or contribute to any inflammation in that area?

A. Without the foci or the external foreign body, there's no source or chronic site for the inflammation to setup.

Q. So what you have talked about and published with respect to obesity doesn't play any role in any inflammation that Mrs. Morrow may have in any part of her body? You are able to wall that off and just say it can affect anything else but not the vagina?

MR. KOTT: Object to the form.

THE WITNESS: At this time this procedure was advocated as an alternative for traditional therapies for morbid obese women, so it was

actually advocated as an alternative method for these patients.

BY MS. MOORE:

Q. And so the answer to my question is Mrs. Morrows' morbid obesity may cause inflammation in every other part of her body but the vagina?

A. But if you have no alternative exogenous mesh there, there's foci for that to setup.

Q. So the answer is her morbid obesity would cause the inflammation in any part of her body but the vagina?

MR. KOTT: Objection.

THE WITNESS: I did not say that. I said there was an implanted device that was said to be implanted that was safer for obese women, because of the co-morbidity and complications associated with surgery. The implant of this foreign body created a foci for the inflammation to be involved with and create a chronic foci for exacerbation of this inflammation of the foreign body reaction, created the contracture and everything associated with the potential issues.

BY MS. MOORE:

Q. Move to strike as non-responsive.

My question is, you have acknowledged on your blog that obesity can cause inflammation and that's something you're very concerned about, correct?

A. Yes.

Q. And in a patient who is morbid obese and has been in that condition for some time, that patient will have inflammation, correct?

A. That's absolute.

Q. Now in Mrs. Morrow's case, will that inflammation be throughout the body or throughout the body but not in the vagina?

A. It will be --

MR. KOTT: Objection.

THE WITNESS: -- throughout the body but with the implant, wherever it could be, whether it be in the abdomen, whether it be in the vagina, wherever it be, you're adding a foreign body which is going to be attacked by your immune system. And thus if you are hyperstimulated with your immune system with a chronic inflammatory state that's not regulated, you are setting up a foci for that

problem.

MS. KOTT: Time.

MS. MOORE: Am I out of time? I think the Judge will allow me to have one last question.

THE WITNESS: Try that getting on the plane, one more minute.

MS. MOORE: Believe me, I've tried that and they slam the door in my face. Believe me there's no sympathy. I think I'm done. Thank you.

VIDEOGRAPHER: We are going off. The time is 12:37.

(Deposition concluded at 12:37 p.m.)

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

NATHAN W. GOODYEAR, M.D. DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires:_____

_____

Notary Public

REPORTER CERTIFICATE

STATE OF TENNESSEE

COUNTY OF KNOX

I, Michele Faconti, RPR, Licensed Court Reporter, LCR #667, in and for the State of Tennessee, do hereby certify that the deposition of Nathan W. Goodyear, M.D., taken on March 4th, 2016, was reported by me and that the foregoing transcript, pages 1 through 195, inclusive, is a true and accurate record to the best of my knowledge, skills and ability.

I further certify that I am not related to, nor an employee or counsel of any of the parties to the action as defined under T.C.A. Section 24-9-136, nor am I financially interested in the outcome of this case. Read and sign not waived.

In witness thereof, I have hereunto set my hand on this 16th day of March, 2016.

_____

Michele Faconti: 03/16/16 22:32:01 AM; Knoxville Tennessee; TN LCR 667